BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE

Faculty of Pharmaceutical Sciences
Doctor of Pharmacy
Pharm D.
New Syllabus

BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY)

'A' GRADE AWARDED BY GOVT OF INDIA
'A+' GRADE REACCREDITATION BY NAAC

Faculty of Pharmaceutical Sciences

Doctor of Pharmacy

Pharm D.

PROGRAMME STRUCTURE & SYLLABUS

w.e.f. 2009

Pharm D. 2009

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
'A' GRADE AWARDED BY GOVT OF INDIA
'A+' GRADE REACCREDITATION BY NAAC

FACULTY OF PHARMACEUTICAL SCIENCES

Pharm D.

Programme Structure and Syllabus

w.e.f. 2009
Pharm D. 2009

Bharati Vidyapeeth (Deemed to be University), Pune

Bharati Vidyapeeth, the parent organization of this University is one of the largest educational organizations in the country. It has 180 educational units under its umbrella including 80 Colleges and Institutes of conventional and professional disciplines.

The Ministry of Human Resource Development, Government of India on the recommendations of the University Grants Commission accorded the status of "Deemed to be University" initially to a cluster of 12 units of Bharati Vidyapeeth. Subsequently, 17 additional colleges / institutes were brought within the ambit of Bharati Vidyapeeth University wide various notifications of the Government of India. Bharati Vidyapeeth (Deemed to be University) commenced its functioning on 26th April, 1996.

Constituent Units of Bharati Vidyapeeth (Deemed to be University)

1. BVDU Medical College, Pune.
2. BVDU Dental College & Hospital, Pune
3. BVDU College of Ayurved, Pune
4. BVDU Homoeopathic Medical College, Pune
5. BVDU College of Nursing, Pune
6. BVDU Yashwantrao Mohite College of Arts, Science & Commerce, Pune.
7. BVDU New Law College, Pune
8. BVDU Social Sciences Centre (M.S.W.), Pune
9. BVDU Yashwantrao Chavan Institute of Social Science Studies & Research, Pune.
10. BVDU Centre for Research & Development in Pharmaceutical Sciences & Applied Chemistry, Pune
11. BVDU College of Physical Education, Pune.
12. BVDU Institute of Environment Education & Research, Pune
13. BVDU Institute of Management & Entrepreneurship Development, Pune
14. BVDU Poona College of Pharmacy, Pune
15. BVDU College of Engineering, Pune
16. BVDU Interactive Research School in Health Affairs (IRSHA), Pune
17. BVDU Rajiv Gandhi Institute of Information Technology & Biotechnology, Pune
18. BVDU College of Architecture, Pune
19. BVDU Abhijit Kadam Institute of Management & Social Sciences, Solapur
20. BVDU Institute of Management, Kolhapur
21. BVDU Institute of Management & Rural Development administration, Sangli
22. BVDU Institute of Management & Research, New Delhi
23. BVDU Institute of Hotel Management & Catering Technology, Pune
24. BVDU Yashwantrao Mohite Institute of Management, Malakapur-Karad
25. BVDU Medical College & Hospital, Sangli
26. BVDU Dental College & Hospital, Mumbai
27. BVDU Dental College & Hospital, Sangli
28. BVDU College of Nursing, Sangli
29. BVDU College of Nursing, Navi Mumbai

The status of university was given to a cluster of these colleges and institutes in appreciation of the high level of their academic excellence and for their potential for further growth.

During the last 20 years or so, the University has achieved higher pinnacles of academic excellence and has established its reputation to such an extent that it attracts students not only from various parts of India but also from abroad. According to a survey conducted by Association of Indian Universities, this University is one among the top ten Universities in the country preferred by the overseas students for admissions. At present, there are more than 850 overseas students from 47 countries on the rolls of constituent units of this University.

During the last 20 years, there has been tremendous academic expansion of the University. It now conducts in all 305 courses in its constituent units, of them 108 are Post Graduate, 45 are Under Graduate and 55 Diploma level courses. 12 Fellowship and 5 certificate courses. All the professional courses which the University conducts such as those of Medicine, Dentistry, Engineering etc., have approval of the respective statutory councils, viz., Medical Council of India, Dental Council of India, All India Council for Technical Education etc.

The University is a throbbing center of research activities and has launched Ph.D. programmes in 77 subjects and M.Phil in 3 subjects. It has also introduced quite few innovative academic programmes such as Masters in Clinical Optometry, M.Tech. in Nano Technology etc.

The University's performance and achievements were assessed by the "National Assessment and Accreditation Council" and it was reaccredited with a prestigious "A" grade in 2011. Some programmes of the constituent units such as College of Engineering at Pune, Management Institute in Delhi and others have also been accredited by "National Board of Accreditation". Three constituent units of Bharati Vidyapeeth (Deemed to be University) are also the recipients of ISO 9001-2001 certifications.

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
POONA COLLGE OF PHARMACY, PUNE

Bharati Vidyapeeth's Poona College of Pharmacy was established in 1981. This college has got approval and recognition of All India Council of Technical Education, New Delhi, Pharmacy Council of India, New Delhi and Bharati Vidyapeeth (Deemed to be University). Earlier the college was affiliated to University of Poona and Maharashtra University of Health Sciences. Now it is a constituent unit of Bharati Vidyapeeth (Deemed to be University). The College conducts B.Pharm, M.Pharm (in Pharmaceutics, Pharm. Chemistry, Pharmacology, Pharmacognosy and Quality Assurance Techniques). The college is housed in beautiful building and located in our bewitching teaching complex at Erandwane, Paud Road, Pune. The excellence which this college has achieved during these years in Pharmacy education is mainly due to its experienced and qualified teaching faculty and the infrastructural facilities of high quality provided in the college. The college has excellent library with modern books on pharmacy. The college also provides hostel facilities on a limited scale to our students both boys and girls.

As soon as the college came under the ambit of Bharati Vidyapeeth (Deemed to be University), the syllabus of B.Pharm and M.Pharm Course was revised and upgraded with the help of eminent experts in the pharmacy and the same was approved by University Authorities. While doing so the guidelines given by UGC, AICTE, Pharmacy Council of India, and the societal needs have been taken into consideration.

VISION:

To be recognized as a premier pharmacy institution of academic excellence.

MISSION STATEMENT:

1) To produce competent pharmacists catering to the needs of Industry, Academia, Research and Society.
2) To create a centre of excellence for education and research in the field of pharmacutical sciences.
3) To contribute our humble share to ensure the well-being and to reduce the suffering of mankind.

PROGRAMME EDUCATIONAL OBJECTIVES (PEO)

1) To provide a comprehensive pharmaceutical education leading to B. Pharm. Degree.
2) To integrate pharmacy knowledge and skills with pharmaceutical research so as to increase inclination for higher studies and research.
3) To develop pharmacists to contribute effectively in the social health care system.
4) To provide hands on training through state of art infrastructure to meet challenges of pharmacy profession.
5) To inculcate leadership and entrepreneurship capabilities in future pharmacists.

PROGRAMME OUTCOMES (POS)

On completion of the B. Pharm. programme, a student will be able to:

1. Demonstrate knowledge of the basic pharmaceutical sciences and the ability to acquire, manage and use current information for problem solving.
2. Describe the synthesis, formulation, analysis and pharmacological aspects of drugs and pharmaceuticals.
3. Identify the rules and regulations involved in the drug discovery and development, manufacture, distribution and sale of medicines.
4. Observe record, analyze, criticize, organize, improvise and manage documents, data and information related to pharmaceutical products and practices.
5. Develop problem-based learning approach and analytical thinking in his/her academic and professional life.
6. Demonstrate the ability to plan and implement professional activities.
7. Act efficiently as a leader in the diverse areas of the profession.
8. Write, interpret and communicate effectively and scientifically.
9. Apply the knowledge and skills gained through education to gain recognition in professional circle and society.
10. Partnering with other health care communities to provide innovative solutions.
11. Create awareness in society about the effective and safe use of medicines.
12. Demonstrate eco-friendly products and processes to maintain public health.
13. Imbibe ethical practices and moral values in personal and professional endeavors.
14. Tackle future challenges through lifelong learning.

[PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and Family Welfare

(Pharmacy Council of India)

New Delhi, 10th May, 2008.

Pharm.D. Regulations 2008

Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948).

(As approved by the Government No.V.13013/1/2007-PMS, dated the 13th Council of India). of India, Ministry of Health vide, letter March, 2008 and notified by the Pharmacy No.14-126/2007-PCI. — In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations, namely: -

CHAPTER-I

1) Short title and commencement. –
    a. These regulations may be called the Pharm.D. Regulations 2008.
    b. They shall come into force from the date of their publication in the official Gazette.
2) Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

CHAPTER-II

3.Duration of the course. –

a) Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

Phase I– consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.

b) Pharm.D. (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one-year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I– consisting of First and Second academic year.

Phase II – consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.

4. Minimum qualification for admission to. –

a) Pharm.D. Part-I Course – A pass in any of the following examinations -

1. 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects:
2. Mathematics or Biology.
    a. A pass in D.Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.
    b. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

b) Pharm.D. (Post Baccalaureate) Course -

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –

(i) Pharm.D. Programme – 30 students.

(ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.

6. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.

7. Course of study. – The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

T A B L E S

First Year:

S.No.	**Name of Subject**	**No. of hours of Theory**	**No. of hours of Practical**	**No. of hours of Tutorial**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	**16**	**18**	**6 = (40)**

* For Biology

Second Year:

S.No	**Name of Subject**	**No. of hours of Theory**	**No. of hours of Practical**	**No. of hours of Tutorial**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	**17**	**9**	**6 = 32**

Third Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	**16**	**15**	**5 = 36**

Fourth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	**15**	**12**	**6 = 33**

Fifth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours Of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	**8**	**20**	**4 = 32**

* Attending ward rounds on daily basis.

Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

(i) Six months in General Medicine department, and

(ii) Two months each in three other speciality departments

8. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.

9. Approval of the authority conducting the course of study.

(1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.

(2) Any person or pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.

(3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

10. Examination.

(1) Every year there shall be an examination to examine the students.

(2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.

(3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below:

T A B L E S

First Year examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/ Biology	70	30	100	70*	30*	100*
				600			600 = 1200

* for Biology.

Second Year examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			300 = 900

Third Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 100

Fourth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

Fifth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)
70 marks – Thesis work

11. Eligibility for appearing Examination.— Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.

12. Mode of examinations.—

(1) Theory examination shall be of three hours and practical examination shall be of four hours duration.

(2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.

(3) Practical examination shall also consist of a viva –voce (Oral) examination.

(4) Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

13. Award of sessional marks and maintenance of records.—

(1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.

(2) There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.

(3) The sessional marks in practicals shall be allotted on the following basis:-

(i) Actual performance in the sessional examination (20 marks)

(ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10 marks)

14. Minimum marks for passing examination. — A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.

15. Eligibility for promotion to next year. — All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.

16. Internship. — (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.

(2) Every student has to undergo one-year internship as per Appendix-C to these regulations.

17. Approval of examinations. — Examinations mentioned in regulations 10 to12 and 14 shall be held by the examining authority hereinafter referred to as the university, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the examining authority concerned fulfills the conditions as specified in Appendix–D to these regulations.

18. Certificate of passing examination. — Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

CHAPTER-III
Practical training

19. Hospital posting.— Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.

20. Project work. — (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.

(2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

21. Objectives of project work. — The main objectives of the project work is to—

(i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and

(ii) develop the students in data collection, analysis and reporting and interpretation skills.

22. Methodology. — To complete the project work following methodology shall be adopted, namely: —

(i) students shall work in groups of not less than two and not more than four under an authorised teacher;

(ii) project topic shall be approved by the Head of the Department or Head of the Institution;

(iii)project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;

(iv) project work shall be approved by the institutional ethics committee;

(v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and

(vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

23. Reporting .— (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution

(2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.
(3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

24. Evaluation.— The following methodology shall be adopted for evaluating the project work—

(i) Project work shall be evaluated by internal and external examiners.

(ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).

(iii)Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:

	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)

(v) Final evaluation of project work shall be done on the following items:

	Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

APPENDIX-A

(See regulation 8)

PHARM.D. SYLLABUS

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives:**
   a. describe the structure (gross and histology) and functions of various organs of the human body;
   b. describe the various homeostatic mechanisms and their imbalances of various systems;
   c. identify the various tissues and organs of the different systems of the human body;
   d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
   e. appreciate coordinated working pattern of different organs of each system; and
   f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

2. **Course Outcomes:**
   1. Explain the terminologies related to human anatomy and physiology.
   2. Describe the structures, functions, and synchronous working of various systems of human body.
   3. Outline various technologies for evaluating physiological functions.
   4. Summarize the impact of social and environmental factors on body system
   5. Interpret the imbalance of homeostasis responsible for various diseases
   6. Discuss the common disorders prevalent in the society

3. **Course materials: Text books**
   a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.
   b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology.

Publisher: Churchill Livingstone, Edinburg.

Reference books

a. Guyton arthur, C. Physiology of human body. Publisher: Holtsaunders.
b. Chatterjee,C.C. Human physiology. Volume 1&11. Publisher: medical allied agency, Calcutta.
c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
d. Gray's anatomy. Publisher:Churchill Livingstone, London.

4. Lecture wise program: Topics

1. Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)
2. Structure of cell – its components and their functions.
3. Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
4. a) Osseous system - structure, composition and functions of the
   b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

5. Haemopoetic System

a) Composition and functions of blood
b) Haemopoesis and disorders of blood components (definition of disorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation

6. Lymph

a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)

7. Cardiovascular system

a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders

Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

8. Respiratory system

a) Anatomy of respiratory organs and functions
b) Mechanism / physiology of respiration and regulation of respiration
c) Transport of respiratory gases
d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

9. Digestive system

a) Anatomy and physiology of GIT
b) Anatomy and functions of accessory glands of GIT
c) Digestion and absorption
d) Disorders of GIT (definitions only)

10. Nervous system

a) Definition and classification of nervous system
b) Anatomy, physiology and functional areas of cerebrum
c) Anatomy and physiology of cerebellum
d) Anatomy and physiology of mid brain
e) Thalamus, hypothalamus and Basal Ganglia
f) Spinal card: Structure & reflexes – mono-poly-planter
g) Cranial nerves – names and functions
h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

11. Urinary system

a) Anatomy and physiology of urinary system
b) Formation of urine
c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
d) Clearance tests and micturition

12. Endocrine system

a) Pituitary gland
b) Adrenal gland
c) Thyroid and Parathyroid glands
d) Pancreas and gonads

13. Reproductive system

a) Male and female reproductive system
b) Their hormones – Physiology of menstruation
c) Spermatogenesis & Oogenesis
d) Sex determination (genetic basis)
e) Pregnancy and maintenance and parturition
f) Contraceptive devices

14. Sense organs

a) Eye
b) Ear
c) Skin
d) Tongue & Nose

15. Skeletal muscles

a) Histology
b) Physiology of Muscle contraction
c) Physiological properties of skeletal muscle and their disorders (definitions)

16. Sports physiology

a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
c) Drugs and athletics

1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Describe the histology of various tissues.
2. Analyze blood samples for hematological parameters and correlate with clinical conditions.
3. Discuss the anatomy and physiology of various human systems with charts and models.
4. Identify bones and explain their anatomy and physiology.
5. Interpret the physiological feedback mechanisms.
6. Explain the importance of hematological parameters, health and family planning devices to the society.

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
   (a) Epithelial tissue.
   (b) Muscular tissue.
2. Study of tissues of human body
   (a) Connective tissue.
   (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
   (a) Erythrocyte Sedimentation Rate.
   (b) Hemoglobin content of Blood.
   (c) Bleeding time & Clotting time.
8. Determination of
   (a) Blood Pressure.

(b) Blood group.

9. Study of various systems with the help of charts, models & specimens
   (a) Skeleton system part I-axial skeleton.
   (b) Skeleton system part II- appendicular skeleton.
   (c) Cardiovascular system.
   (d) Respiratory system.
   (e) Digestive system.
   (f) Urinary system.
   (g) Nervous system.
   (h) Special senses.
   (i) Reproductive system.
10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastroenemius sciatic nerve preparation
14. To record simple summation curve using gastroenemius sciatic nerve preparation.
15. To record simple effect of temperature using gastroenemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastroenemius sciatic nerve preparation.
17. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for egularity, promptness, viva-voce and record maintenance).

1.2 PHARMACEUTICS (THEORY)

Practical : 3 Hrs./Week

1. **Objectives**: Upon the completion of the course the student should be able to:
   a. know the formulation aspects of different dosage forms;
   b. do different pharmaceutical caluculation involved in formulation;
   c. formulate different types of dosage forms; and
   d. appreciate the importance of good formulation for effectiveness.

2. **Course Outcomes:**
   i. Evaluate the prescription for rational drug therapy
   ii. Explain principles of modern dispensing practices
   iii. Recommend patients about pharmaceutical dosage forms
   iv. Compound and dispense dosage forms
   v. Practice ethics in community pharmacy
   vi. Apply basic principles and calculations in formulation development

3. **Course materials: Text bookk**
   a. Cooper and Gunns Dispensing for pharmacy students.
   b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

   c. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
   d. Remington's Pharmaceutical Sciences.
   e. Register of General Pharmacy by Cooper and Gunn.
   f. General Pharmacy by M.L.Schroff.

4. **Lecture wise programme: Topics**

1 a. Introduction to dosage forms - classification and definitions
   b. Prescription: definition, parts and handling
   c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.

2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.

3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.

4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.

5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.

6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.

8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.

9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

10 Pharmaceutical calculations.

11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.

12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1.2 PHARMACEUTICS (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Understanding the basic knowledge in the formulation aspects of different dosage forms.
2. Formulate the different dosage forms such as solid and liquid orals
3. Recommend patients about pharmaceutical dosage forms and Create patient counselling aids
4. Apply knowledge in formulating various pharmaceutical dosage forms.
5. Practice ethics in community pharmacy
6. Use of practical knowledge in the field of incompatibility and method to overcome

List of Experiments:

1. **Syrups**
   a. Simple Syrup I.P
   b. Syrup of Ephedrine Hcl NF
   c. Syrup Vasaka IP
   d. Syrup of ferrous Phosphate IP
   e. Orange Syrup

2. **Elixir**
   a. Piperizine citrate elixir BP
   b. Cascara elixir BPC
   c. Paracetamol elixir BPC

3. **Linctus**
   a. Simple Linctus BPC
   b. Pediatric simple Linctus BPC

4. **Solutions**
   a. Solution of cresol with soap IP
   b. Strong solution of ferric chloride BPC
   c. Aqueous Iodine Solution IP
   d. Strong solution of Iodine IP
   e. Strong solution of ammonium acetate IP

5. **Liniments**
   a. Liniment of turpentine IP*
   b. Liniment of camphor IP

6. **Suspensions***
   a. Calamine lotion
   b. Magnesium Hydroxide mixture BP

7. **Emulsions***
    a. Cod liver oil emulsion
    b. Liquid paraffin emulsion

8. **Powders***
    a. Eutectic powder
    b. Explosive powder
    c. Dusting powder
    d. Insufflations

9. **Suppositories***
    a. Boric acid suppositories
    b. Chloral suppositories

10. **Incompatibilities**
    c. Mixtures with Physical
    d. Chemical & Therapeutic incompatibilities

*colourless bottles required for dispensing Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives of the Subject** (Know, do, appreciate):

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
e. do the qualitative analysis and determination of biomolecules in the body fluids.

2. **Course Outcomes:**

1. Gain insights into the catalytic functions of enzymes and recognize the significance of isoenzymes in the diagnosis of various diseases.
2. Comprehend the metabolic processes of biomolecules in both normal physiological states and during the manifestation of metabolic disorders.
3. DNA replication, mutation processes, and mechanisms for DNA repair.
4. Know the biochemical principles of organ function tests of kidney, liver and endocrine gland
5. Perform qualitative analysis and determine the presence of biomolecules in body fluids.
6. Understand the principle for performing various biochemical assays

Text books (Theory)

a. Harpers review of biochemistry - Martin
b. Text book of biochemistry – D.Satyanarayana
c. Text book of clinical chemistry- Alex kaplan &Laverve L.Szabo

Reference books (Theory)

a. Principles of biochemistry -- Lehninger
b. Text book of biochemistry -- Ramarao
c. Practical Biochemistry-David T.Plummer.
d. Practical Biochemistry-Pattabhiraman.

3. **Lecture wise programme:**

Topics

1 Introduction to biochemistry: Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.

2 Enzymes: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.

3 Carbohydrate metabolism: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

4 Lipid metabolism: Oxidation of saturated (□-oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea).

5 Biological oxidation: Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;

6 Protein and amino acid metabolism: protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.

7 Nucleic acid metabolism: Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.

8 Introduction to clinical chemistry: Cell; composition; malfunction; Roll of the clinical chemistry laboratory.

9 The kidney function tests: Role of kidney; Laboratory tests for normal function includes-

   a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
   b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
   c) Urine concentration test
   d) Urinary tract calculi. (stones)

10 Liver function tests: Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.

   a) Test for hepatic dysfunction-Bile pigments metabolism.
   b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
   c) Dye tests of excretory function.
   d) Tests based upon abnormalities of serum proteins.

11 Lipid profile tests: Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

12 Immunochemical techniques for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases. Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

13 Electrolytes: Body water, compartments, water balance, and electrolyte distrubution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Course Outcomes:

1. Identification of Urinary constituents and Abnormalities for clinical diagnostics
2. Application of Quantitative Techniques in laboratory tests.
3. Conduct Serum Biochemical Analysis.
4. Explore Enzyme Activity and the factors affecting it.
5. Precision in the preparation of Solutions and reagents useful in clinical testing.
6. Utilize Specialized Diagnostic Techniques in diagnostics.

Title of the Experiment:

1. Qualitative analysis of normal constituents of urine.*
2. Qualitative analysis of abnormal constituents of urine.*
3. Quantitative estimation of urine sugar by Benedict's reagent method.**
4. Quantitative estimation of urine chlorides by Volhard's method.**
5. Quantitative estimation of urine creatinine by Jaffe's method.**
6. Quantitative estimation of urine calcium by precipitation method.**
7. Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
8. Preparation of Folin Wu filtrate from blood.*
9. Quantitative estimation of blood creatinine.**
10. Quantitative estimation of blood sugar Folin-Wu tube method.**
11. Estimation of SGOT in serum.**
12. Estimation of SGPT in serum.**
13. Estimation of Urea in Serum.**
14. Estimation of Proteins in Serum.**
15. Determination of serum bilirubin**
16. Determination of Glucose by means of Glucoseoxidase.**
17. Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
18. Study of factors affecting Enzyme activity. (pH & Temp.)**
19. Preparation of standard buffer solutions and its pH measurements (any two)*
20. Experiment on lipid profile tests**
21. Determination of sodium,calcium and potassium in serum.**

** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives:**
   a. This course is designed to impart a very good knowledge about a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
   b. Some important physical properties of organic compounds;
   c. Free radical/ nucleophyllic [alkyl/ acyl/ aryl] /electrophyllic substitution, free radical/ nucleophyllic / electrophyllic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
   d. Some named organic reactions with mechanisms; and
   e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. Course Outcomes:

1. Understand the principles and procedures of synthesis of drugs
2. Explain need and basic principle and applications of different chemical synthesis and methods thereof.
3. Have knowledge of the chemistry of the organic pharmaceuticals
4. Appreciate the importance of organic pharmaceuticals in preventing and curing the disease.
5. To highlight the nature of the organic compounds used in Pharmaceuticals as drugs
6. Critical understanding of key reactions used in synthesis of therapeutics.

3. Course materials: Text books

a. T.R.Morrison and R. Boyd - Organic chemistry,
b. Bentley and Driver-Text book of Pharmaceutical chemistry
c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

Reference books

a. Organic chemistry – J.M.Cram and D.J.Cram
b. Organic chemistry- Brown
c. Advanced organic chemistry- Jerry March, Wiley
d. Organic chemistry- Cram and Hammered, Pine Hendrickson

4. Lecture wise programme: Topics

1 Structures and Physical properties:

a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non-ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
b. Acids and bases, Lowry bronsted and Lewis theories
c. Isomerism

2 Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides and Cycloalkanes.

3 Free radicals chain reactions of alkane: Mechanism, relative reactivity and stability

4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.

5 Nuclophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

7 Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

8 Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

9 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substituion in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

10 Elecrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic

aromatic substitution in alkyl benzene, side chain halogination of alkyl benzene, resonance stabilization of benzyl radical.

11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.

14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.

15 Oxidation reduction reaction.

16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Course Outcomes:

1. Learn about the many functional groups of organic medicines, the properties of these compounds, and the techniques for synthesizing these compounds.
2. Recognize the identification of pharmaceutical organic chemicals and their role in medicine.
3. Acquire knowledge and skills on Organic functional group detection of medicine and drugs
4. Identify/confirm the unknown organic compounds.
5. Familiarize with the fundamentals of synthesis of organic chemicals that are vital to the pharmaceutical industry.
6. Application of different type of organic reactions

Course Content

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilde / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-napthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Antharaquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotolune
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by:

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory : 2 Hrs. /Week

1. **objectives:** Upon completion of the course student shall be able to:
   a. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
   b. know the analysis of the inorganic pharmaceuticals their applications; and
   c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

2. **Course Outcomes:**
   1. Understand the principles and procedures of analysis of drugs
   2. Explain need and basic principle and applications of different titrations.
   3. Have knowledge of the analysis of the inorganic pharmaceuticals
   4. Appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.
   5. To highlight the limit of the inorganic impurities in Pharmaceuticals
   6. Critical analysis of radiopharmaceutical as therapeutics.

3. **Course materials: Text books**
   a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
   b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol -I & Vol-II
   c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

Reference books

a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
c. Analytical chemistry principles by John H. Kennedy
d. I.P.1985 and 1996, Govt. of India, Ministry of health

4. Lecture wise programme: Topics

1 Errors
2 Volumetric analysis
3 Acid-base titrations
4 Redox titrations
5 Non aqueous titrations
6 Precipitation titrations
7 Complexometric titrations
8 Theory of indicators
9 Gravimetry
10 Limit tests
11 Medicinal gases
12 Acidifiers
13 Antacids

14 Cathartics
15 Electrolyte replenishers
16 Essential Trace elements
17 Antimicrobials
18 Pharmaceutical aids
19 Dental Products
20 Miscellaneous compounds
21 Radio Pharmaceuticals

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Learn about the many groups of inorganic medicines, the sources of impurities, and the techniques for identifying impurities in pharmaceuticals.
2. Recognize the analysis of pharmaceutical inorganic chemicals and their role in medicine.
3. Acquire knowledge and skills on volumetric analytical methodologies.
4. Identify/confirm the unknown inorganic anions and cations.
5. Familiarize with the fundamentals of synthesis of inorganic chemicals that are vital to the pharmaceutical industry.
6. Application of different type of titration

Course Content

1. Limit test (6 exercises)
    a. Limit test for chlorides
    b. Limit test for sulphates
    c. Limit test for iron
    d. Limit test for heavy metals
    e. Limit test for arsenic
    f. Modified limit tests for chlorides and sulphates
2. Assays (10 exercises)
    a. Ammonium chloride- Acid-base titration
    b. Ferrous sulphate- Cerimetry
    c. Copper sulpahte- Iodometry
    d. Calcilugluconate- Complexometry
    e. Hydrogen peroxide – Permanganometry
    f. Sodium benzoate – Nonaqueous titration
    g. Sodium chloride – Modified volhard's method
    h. Assay of KI – KIO3 titration
    i. Gravimetric estimation of barium as barium sulphate
    j. Sodium antimony gluconate or antimony potassium tartarate
3. Estimation of mixture (Any two exercises)
    a. Sodium hydroxide and sodium carbonate
    b. Boric acid and Borax
    c. Oxalic acid and sodium oxalate
4. Test for identity (Any three exercises)
    d. Sodium bicarbonate
    e. Barium sulphate
    f. Ferrous sulphate
    g. Potassium chloride

5. Test for purity (Any two exercises)
    1. Swelling power in Bentonite
    2. Acid neutralising capacity in aluminium hydroxide gel
    3. Ammonium salts in potash alum
    4. Adsorption power heavy Kaolin
    5. Presence of Iodates in KI
6. Preparations (Any two exercises)
    a. Boric acids
    b. Potash alum
    c. Calcium lactate
    d. Magnesium suphate

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment1&2	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory: 3 Hrs. /Week

REMEDIAL MATHEMATICS:

1. **Scope and objectives:** This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.
2. Upon completion of the course the student shall be able to: –
   g. Know Trignometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
   h. solve the problems of different types by applying theory; and
   i. appreciate the important applications of mathematics in pharmacy.
3. Course materials: Text books
   a. Differential calculus by Shantinarayan
   b. Text book of Mathematics for second year pre-university by Prof. B. M. Sreenivas

Reference books

a. Integral calculus by Shanthinarayan
b. Engineering mathematics By B.S.Grewal
c. Trigonometry Part-I By S.L.Loney

4. Lecture wise programme:

Topics

1	Algebra: Determinants, Matrices
2	Trigonometry: Sides and angles of a triangle, solution of triangles
3	Analytical Geometry: Points, Straight line, circle, parabola
4	Differential calculus: Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
5	Integral Calculus: Definite integrals, integration by substitution and by parts, Properties of definite integrals.
6	Differential equations: Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
7	Laplace transform: Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

BIOLOGY:

1. Scope and objectives: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduces to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.
2. Course materials: Text books
   a. Text book of Biology by S.B.Gokhale
   b. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

a. A Text book of Biology by B.V.Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. Lecture wise programme:

Topic

PART – A

1. Introduction
2 General organization of plants and its inclusions
3 Plant tissues
4 Plant kingdom and its classification
5 Morphology of plants
6 Root, Stem, Leaf and Its modifications
7 Inflorescence and Pollination of flowers
8 Morphology of fruits and seeds
9 Plant physiology
10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

1 Study of Animal cell
2 Study animal tissues
3 Detailed study of frog
4 Study of Pisces, Raptiles, Aves
5 Genearal organization of mammals
6 Study of poisonous animals

1.6 BIOLOGY (PRACTICAL)

Course Content

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives of the Subject:** Upon completion of the subject student shall be able to –
    h. describe the etiology and pathogenesis of the selected disease states;
    i. name the signs and symptoms of the diseases; and
    j. mention the complications of the diseases.

2. Course Outcomes:

1. Summarize the concepts of cell injury and adaptation.
2. Comprehend the etiology and pathogenesis of diseases.
3. Interpret the disease course and predict the complications of the disease.
4. Corelate the pathological changes with clinical course and identify the therapeutic targets.
5. Describe the factors influencing transplantation of organs.
6. Communicate effectively the disease prevention measures to the society.

Text books (Theory)

a. Pathologic basis of disease by- Cotran, Kumar, Robbins
b. Text book of Pathology- Harsh Mohan
c. Text book of Pathology- Y.M. Bhinde

Reference books (Theory)

a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. Detailed syllabus and lecture wise schedule: Chapter

1. Basic principles of cell injury and Adaptation

a) Causes, Pathogenesis and morphology of cell injury
b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

2. Inflammation

a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
b) Repairs of wounds in the skin, factors influencing healing of wounds

3. Diseases of Immunity

a) Introduction to Tand B cells
b) MHC proteins or transplantation antigens
c) Immune tolerance -Hypersensitivity

Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs - Autoimmunity Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.

- Acquired immune deficiency syndrome (AIDS)
- Amylodosis

4. **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.

5. **Types of shock, mechanisms, stages and management**
6. **Biological effects of radiation**

7. **Environmental and nutritional diseases**
   i. Air pollution and smoking- SO2, NO, NO2, and CO
   ii. Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.

8. Pathophysiology of common diseases

a. Parkinsonism
b. Schizophrenia
c. Depression and mania
d. Hypertension,
e. Stroke (ischaemic and hemorrhage)
f. Angina, CCF, Atherosclerosis, Myocardial infarction
g. Diabetes Mellitus
h. Peptic ulcer and inflammatory bowel diseases
i. Cirrhosis and Alcoholic liver diseases
j. Acute and chronic renal failure
k. Asthma and chronic obstructive airway diseases

9. Infectious diseases:

Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis-infective hepatitis.

4.Assignments:

Title of the Experiment

1 Chemical Mediators of inflammation
2 Drug Hypersensitivity
3 Cigarette smoking & its ill effects
4 Biological Effects of Radiation
5 Etiology and hazards of obesity

6 Complications of diabetes
7 Diagnosis of cancer
8 Disorders of vitamins
9 Methods in Pathology-Laboratory values of clinical significance
10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory: 3 Hrs. /Week

1. Objectives of the Subject:

Upon completion of the subject student shall be able to –

a. know the anatomy, identification, growth factors and sterilization of microorganisms;
b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
c. do estimation of RNA and DNA and there by identifying the source;
d. do cultivation and identification of the microorganisms in the laboratory;
e. do identification of diseases by performing the diagnostic tests; and
f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

2. Course Outcomes:

1. Illustrate the basic knowledge of microbiology with pharmaceutical sciences.
2. Apply techniques for identification and isolation of microorganisms.
3. Understand process of sterilization and disinfection
4. Conceptualize the significance of immunological reactions.
5. Implement of diagnostic testing methods for infectious disease
6. Justify the use of microorganisms considering the ecological and ethical issues.

Text books (Theory)

a. Vanitha Kale and Kishor Bhusari ― Applied Microbiology ‖ Himalaya Publishing house Mumbai.
b. Mary Louis Turgeon ― Immunology and Serology in Laboratory Medicines‖ 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
c. Harsh Mohan, ― Text book of Pathology‖ 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

a. Prescot L.M., Jarley G.P Klein D.A ―Microbiology‖ 2nd- edition Mc Graw Hill Company Inc
b. Rawlins E.A.‖Bentley's Text Book of Pharmaceutics‖ B ailliere Tindals 24-28 London 1988
c. Forbisher ― Fundamentals of Microbiology‖ Philidelphia W.B. Saunders.
d. Prescott L.M. Jarley G.P., Klein.D.A. ― Microbiology.‖2nd edition WMC Brown Publishers, Oxford. 1993
e. War Roitt, Jonathan Brostoff, David male, ― Immunology‖3rd edition 1996, Mosby-year book Europe Ltd, London.
f. Pharmacopoeia of India, Govt of India, 1996.

3. **Detailed syllabus and lecture wise schedule :** Title of the topic

1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.

2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.

3 Nutritional requirements, growth and cultivation of bacteria and virus.
Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.

4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.

5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations.

Brief information on Validation.

6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic,, virucidal activities, evaluation of preservatives in pharmaceutical preparations.

7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity (active and passive) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.

8 Diagnostic tests: Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite.

9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B2 and B12. Standardisation of vaccines and sera.

10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Course Outcomes:

1. Implement good laboratory practices in pharmaceutical microbiology.
2. Prepare, isolate, and identify the culture media for various microorganisms.
3. Assess aseptic conditions in pharmaceutical laboratories as per GLP
4. Apply sterilization and disinfection techniques in pharmacy.
5. Determine the microbial count using modern analytical tools
6. Compute, analyze and record data.

Title of the Experiment:

1. Study of apparatus used in experimental microbiology*.
2. Sterilisation of glass ware's. Preparation of media and sterilisation.*
3. Staining techniques – Simple staining ; Gram's staining ; Negative staining**
4. Study of motility characters*.
5. Enumeration of micro-organisms (Total and Viable)*
6. Study of the methods of isolation of pure culture.*
7. Bio chemical testing for the identification of micro*-organisms.
8. Cultural sensitivity testing for some micro-organisms.*
9. Sterility testing for powders and liquids.*
10. Determination of minimum inhibitory concentration.*
11. Microbiological assay of antibiotics by cup plate method.*
12. Microbiological assay of vitamins by Turbidometric method**
13. Determination of RWC.**
14. Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

1. Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories (other sterization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
   a. Report of recent microbial techniques developed in diagnosing some common diseases.
   b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.

5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives: Upon completion of the course student shall be able to:**
    a. understand the basic principles of cultivation, collection and storage of crude drugs;
    b. know the source, active constituents and uses of crude drugs; and
    c. appreciate the applications of primary and secondary metabolites of the plant.

2. **Course Outcomes:**
    1. Understand the concept and scope of Pharmacognosy with various systems.
    2. Explain the concept of classification of crude drugs including primary and secondary metabolites and natural fibers.
    3. Comprehend the concepts of cultivation and collection of crude drugs for organized and unorganized drugs.
    4. Discover the concepts of processing production, storage, and adulteration of crude drugs.
    5. Describe the various extraction and evaluation techniques for the herbal drugs along with uses and chemical nature.
    6. Carry out the microscopic and morphological evaluation of crude drugs with respect to cellular contents.

3. **Course materials:**

Text books

a. Pharmacognosy by G.E. Trease & W.C.Evans.
b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

Reference books

a. Pharmacognosy by Brady &Tyler.E.
b. Pharmacognosy by T.E.Wallis.
c. Pharmacognosy by C.S. Shah & Qadery.
d. Pharmacognosy by M.A. Iyengar**.**

4. **Lecture wise programme: Topics**
    1. Introduction.
    2. Definition, history and scope of Pharmacognosy.
    3. Classification of crude drugs.
    4. Cultivation, collection, processing and storage of crude drugs.
    5. Detailed method of cultivation of crude drugs.
    6. Study of cell wall constituents and cell inclusions.
    7. Microscopical and powder Microscopical study of crude drugs.
    8. Study of natural pesticides.
    9. Detailed study of various cell constituents.
    10. Carbohydrates and related products.

11. Detailed study carbohydrates containing drugs.(11 drugs)
12. Definition sources, method extraction, chemistry and method of analysis of lipids.
13. Detailed study of oils.
14. Definition, classification, chemistry and method of analysis of protein.
15. Study of plants fibers used in surgical dressings and related products.
16. Different methods of adulteration of crude drugs.

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical : 3 Hrs./Week

Course Outcomes:

1. Evaluate crude drugs based on chemical tests
2. Identify the various leaves on the basis of quantitative microscopy (with camera lucida) like stomatal index, palisade ratio etc.
3. Explain the crude drugs based on microscopical characters
4. Explore different types of methods for standardization of crude drugs, i.e. ash value, foaming index, extractive values etc. along with morphology.
5. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
6. Study of various types values as iodine value, saponification value, ester value, acid value.

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

1. Introduction of Pharmacognosy laboratory and experiments.
2. Study of cell wall constituents and cell inclusions.
3. Macro, powder and microscopic study of Datura.
4. Macro, powder and microscopic study of Senna.
5. Macro, powder and microscopic study of Cassia.cinnamon.
6. Macro, powder and microscopic study of Cinchona.
7. Macro, powder and microscopic study of Ephedra.
8. Macro, powder and microscopic study of Quassia.
9. Macro, powder and microscopic study of Clove
10. Macro, powder and microscopic study of Fennel.
11. Macro, powder and microscopic study of Coriander.
12. Macro, powder and microscopic study of Isapgol.
13. Macro, powder and microscopic study of Nux vomica.
14. Macro, powder and microscopic study of Rauwolfia.
15. Macro, powder and microscopic study of Liquorice.
16. Macro, powder and microscopic study of Ginger.
17. Macro, powder and microscopic study of Podophyllum.
18. Determination of Iodine value.
19. Determination of Saponification value and unsaponifiable matter.
20. Determination of ester value.
21. Determination of Acid value.
22. Chemical tests for Acacia.
23. Chemical tests for Tragacanth.
24. Chemical tests for Agar.

25. Chemical tests for Starch.
26. Chemical tests for Lipids. (castor oil,sesame oil, shark liver oil,bees wax)
27. Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

2.4 PHARMACOLOGY – I (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
   a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
   b. handle and carry out the animal experiments;
   c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
   d. correlate and apply the knowledge therapeutically.

2. Course Outcomes:

1. Describe the fundamental concepts of pharmacology.
2. Relate the molecular basis of drug action with clinical uses.
3. Comprehend the adverse effects and drug interactions.
4. Justify correlation of pharmacology with other bio medical sciences.
5. Apply the pharmacological knowledge in the prevention and treatment of various diseases.
6. Recommend measures to minimize adverse drug effects and drug interactions to the society.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The Pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
c. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical):

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. **Detailed syllabus and lecture wise schedule:** Title of the topic

1. General Pharmacology

a) Introduction, definitions and scope of pharmacology
b) Routes of administration of drugs
c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
d) Pharmacodynamics
e) Factors modifying drug effects
f) Drug toxicity - Acute, sub- acute and chronic toxicity.
g) Pre-clinical evaluations
h) Drug interactions

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. Pharmacology of drugs acting on ANS

a) Adrenergic and antiadrenergic drugs
b) Cholinergic and anticholinergic drugs
c) Neuromuscular blockers
d) Mydriactics and miotics
e) Drugs used in myasthenia gravis
f) Drugs used in Parkinsonism

3. Pharmacology of drugs acting on cardiovascular system

a) Antihypertensives
b) Anti-anginal drugs
c) Anti-arrhythmic drugs
d) Drugs used for therapy of Congestive Heart Failure
e) Drugs used for hyperlipidaemias

4. Pharmacology of drugs acting on Central Nervous System

a) General anesthetics
b) Sedatives and hypnotics
c) Anticonvulsants

d) Analgesic and anti-inflammatory agents
e) Psychotropic drugs
f) Alcohol and methyl alcohol
g) CNS stimulants and cognition enhancers
h) Pharmacology of local anaesthetics

5. Pharmacology of Drugs acting on Respiratory tract

a) Bronchodilators
b) Mucolytics
c) Expectorants
d) Antitussives
e) Nasal Decongestants

6. Pharmacology of Hormones and Hormone antagonists

a. Thyroid and Antithyroid drugs
b. Insulin, Insulin analogues and oral hypoglycemic agents
c. Sex hormones and oral contraceptives
d. Oxytocin and other stimulants and relaxants

7. Pharmacology of autocoids and their antagonists

a. Histamines and Antihistaminics
b. 5-Hydroxytryptamine and its antagonists
c. Lipid derived autocoids and platelet activating factor

2.5 COMMUNITY PHARMACY (THEORY)

Theory: 2 Hrs. /Week

1. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know pharmaceutical care services;
   b. know the business and professional practice management skills in community pharmacies;
   c. do patient counselling & provide health screening services to public in community pharmacy;
   d. respond to minor ailments and provide appropriate medication;
   e. show empathy and sympathy to patients; and
   f. appreciate the concept of Rational drug therapy.

2. Course Outcomes:

1. Understand the role, responsibility establishment procedure and management of community pharmacy
2. Handle and interpret prescriptions to avoid drug-drug and drug-food interaction
3. Implement inventory control and drug management system in community pharmacy
4. Apply ethical practices for rational drug therapy, essential drug and patient counseling
5. Counsel the patients and provide health screening services in the management of minor and chronic diseases
6. Promote the role of community pharmacist in the society to develop professional image

Text Books:

a. Health Education and Community Pharmacy by N.S.Parmar.
b. WHO consultative group report.
c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

a. Handbook of pharmacy – health care.Edt. Robin J Harman. The Pharmaceutical press.
b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

1. Synopsis 10
2. Major Experiment 30

(Counselling of patients with specific diseases – emphasis should be given on

Counselling introduction, content, process and conclusion)

3. Minor Experiment(Ability to measure B.P/ CBG / Lung function) 15
4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management 15
5. Viva – Voce 10

4. Lecture wise programme:

Topics

1. **Definition, scope, of community pharmacy Roles and responsibilities of Community pharmacist**
2. **Community Pharmacy Management**
   a) Selection of site, Space layout, and design
   b) Staff, Materials- coding, stocking
   c) Legal requirements
   d) Maintenance of various registers
   e) Use of Computers: Business and health care soft wares
3. **Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.
4. **Inventory control in community pharmacy**
   Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock
5. **Pharmaceutical care**
   Definition and Principles of Pharmaceutical care.
6. **Patient counselling**
   Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design, & layouts, advisory labels
7. **Patient medication adherence**
   Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
8. **Health screening services**
   Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function and Cholesterol testing
9. **OTC Medication- Definition, OTC medication list & Counselling**
10. **Health Education**
    WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
    Commonly occurring Communicable Diseases, causative agents,
    Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy,
    Syphilis, Gonorrhea and AIDS
    Balance diet, and treatment & prevention of deficiency disorders
    Family planning – role of pharmacist

11. **Responding to symptoms of minor ailments**
    Relevant pathophysiology, common drug therapy to, Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.
12. **Essential Drugs concept and Rational Drug Therapy Role of community pharmacist**
13. **Code of ethics for community pharmacists**

2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualised therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. discuss the controversies in drug therapy;
   i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

2. **Course Outcomes:**
   1. Describe the etiopathogenesis of diseases and the rationale of drug therapy.
   2. Relate the patient specific parameters before initiating drug therapy.
   3. Illustrate the drug therapy controversies.
   4. Sketch individualized therapeutic plan based on diagnosis of patient.
   5. Devise the pharmacotherapeutic care plan in various disease conditions.
   6. Summarize the therapeutic approach to the management of diseases and their monitoring parameters.

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.

b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
d. Applied Therapeutics:The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

f. Relevant review articles from recent medical and pharmaceutical literature.

3. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

1. **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias
2. **Respiratory system:** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

   Endocrine system: Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
3. **General prescribing guidelines for**
   a. Paediatric patients
   b. Geriatric patients
   c. Pregnancy and breast feeding
4. **Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial**
5. **Introduction to rational drug use**

Definition, Role of pharmacist Essential drug concept Rational drug formulations

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. List the subjective-objective parameters.
2. Review the clinical presentation and diagnosis of disease state.
3. Apply the pharmacotherapeutic principles in disease management.
4. Prepare pharmaceutical care plan.
5. Revise the pharmaceutical care plan as per pharmacotherapy problems.
6. Recommend the monitoring parameters and outcome measures.

Practicals:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory: 3 Hrs. /Week

1. Objectives of the Subject Upon completion of the subject student shall be able to:

a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
b. carry out the animal experiments confidently,
c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
d. correlate and apply the knowledge therapeutically.

2.Course Outcomes:

1. Relate the molecular basis of drug action with clinical uses.
2. Comprehend the adverse effects and drug interactions.
3. Understand gene therapy and targeting.
4. Justify correlation of pharmacology with other biomedical sciences.
5. Apply the pharmacological knowledge in the prevention and treatment of various diseases.
6. Recommend measures to minimize adverse drug effects and drug interactions to the society.

Text books (Theory)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The Pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical) :

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3.Detailed syllabus and lecture wise schedule: Title of the topic

1. Pharmacology of Drugs acting on Blood and blood forming agents

a) Anticoagulants
b) Thrombolytics and antiplatelet agents
c) Haemopoietics and plasma expanders

2. Pharmacology of drugs acting on Renal System

a) Diuretics
b) Antidiuretics

3. Chemotherapy

a) Introduction
b) Sulfonamides and co-trimoxazole
c) Penicillins and Cephalosporins
d) Tetracyclins and Chloramphenicol
e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
f) Quinolines and Fluroquinolines
g) Antifungal antibiotics
h) Antiviral agents
i) Chemotherapy of tuberculosis and leprosy
j) Chemotherapy of Malaria
k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
l) Pharmacology of Anthelmintic drugs
m) Chemotherapy of cancer (Neoplasms)

4. Immunopharmacology

Pharmacology of immunosuppressants and stimulants

5. Principles of Animal Toxicology Acute, sub-acute and chronic toxicity

6. The dynamic cell: The structures and functions of the components of the cell

a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
c) DNA replication: General, bacterial and eukaryotic DNA replication.

d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

The Gene: Genome structure and function:

a) Gene structure: Organization and elucidation of genetic code.
b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities.
Oncogenes and tumor suppressor genes.
The gene sequencing, mapping and cloning of human disease genes.
Introduction to gene therapy and targeting.
Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

1. Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
2. Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
3. Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
4. Genes VIII by Lewin, B., (2004)
5. Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
6. Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
7. Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.1 PHARMACOLOGY – II (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Understand the importance of use of animals in drug discovery and development.
2. Apply ethical principles in animal experimentation.
3. Demonstrate the use of common experimental pharmacology instruments.
4. Outline the principles and applications of bioassay
5. Evaluate the effect of drugs using various techniques in experimental pharmacology.
6. Appreciate correlation of pharmacology with related medical sciences.

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three-point method.
8. To record the dose response curve of Histamine using isolated guinea -pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea -pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three-point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
    a) Analgesic property of drug using analgesiometer.
    b) Antiinflammatory effect of drugs using rat-paw edema method.
    c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
    d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
    e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
    f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	**20**	**70**
Duration	**3hrs**	**4hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes:

1. Understand the concept of QA, SQC, TQM and ICH guidelines
2. Integrate physicochemical and electrochemical properties of drugs with analytical methods
3. Comprehend the importance of instrumentation of various analytical techniques
4. Remember the principle, advantages, challenges, and applications of electrochemical analysis
5. Remember the principle, advantages, challenges, and applications of spectroscopic analysis
6. Study of X Ray/ Thermal methods of analysis

Course Content

1. Quality Assurance:

a. Introduction, sources of quality variation, control of quality variation.
b. Concept of statistical quality control.
c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
d. GLP, ISO 9000.
e. Total quality management, quality review and documentation.
f. ICH- international conference for harmonization-guidelines.
g. Regulatory control.

2. Chromatography:

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

a. **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
b. **TLC:** Introduction, principle, techniques, Rf value and applications.
c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
d. Ion-exchange chromatography: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
e. **HPLC:** Introduction, theory, instrumentation, and applications.
f. **HPTLC:** Introduction, theory, instrumentation, and applications.
g. **Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors-Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.

h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
i. **Gel filtration and affinity chromatography:** Introduction, technique, applications.

3. Electrometric Methods:

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

a. **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
b. **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
c. **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. Spectroscopy:

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. Absorption Spectroscopy:

-Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following Detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

-Infrared Spectroscopy: Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectro-meter – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors– Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

-Fluorimetric Analysis: Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

b. Flame Photometry: Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.

c. Atomic Absorption Spectrometry: Introduction, Theory, types of electrodes, instrumentation and applications.

d. Atomic Emission Spectroscopy: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

e. NMR & ESR (introduction only): Introduction, theoretical aspects and applications.

f. Mass Spectroscopy: (Introduction only) – Fragmentation, types of ions produced mass spectrum and applications.

g.Polarimetry: (Introduction only) – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.

h.X-RAY Diffraction: (Introduction only) – Theory, reciprocal lattice concept, diffraction patterns and applications.

i. Thermal Analysis: Introduction, instrumentation, applications, and DSC and DTA.

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Understand the significance of analysis in analytical chemistry by UV spectroscopy
2. Estimation of drugs using Fluorimetric methods for drug analysis
3. Analyze the drugs using colourimetry, Nepheloturbidimetry and Flame photometry
4. Demonstrate analytical skills for evaluation of drugs by HPLC, GC and DSC
5. Observe, record, and communicate experimental data
6. To develop the interpretation skills

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of a acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.

7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory: 3 Hrs. /Week

1. Objectives of the Subject Upon completion of the subject student shall be able to –

a. know the pathophysiology of selected disease states and the rationale for drug therapy
b. know the therapeutic approach to management of these diseases;
c. know the controversies in drug therapy;
d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

2. Course Outcomes:

1. Describe the etiopathogenesis of diseases and the rationale of drug therapy.
2. Relate the patient specific parameters before initiating drug therapy.
3. Illustrate the drug therapy controversies.
4. Sketch individualized therapeutic plan based on diagnosis of patient.
5. Devise the pharmacotherapeutic care plan in various disease conditions.
6. Summarize the therapeutic approach to the management of diseases and their monitoring parameters.

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –Title of the topic

1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis
2. **Musculoskeletal disorders**
   Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
3. **Renal system** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis

5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Course Outcomes:

1. List the subjective-objective parameters.
2. Review the clinical presentation and diagnosis of disease state.
3. Apply the pharmacotherapeutic principles in disease management.
4. Prepare pharmaceutical care plan.
5. Revise the pharmaceutical care plan as per pharmacotherapy problems.
6. Recommend the monitoring parameters and outcome measures.

Practicals:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory: 2 Hrs. /Week

1. **Objectives of the Subject: Upon completion of the subject student shall be able to (Know, do, and appreciate) –**
   a. practice the Professional ethics;
   b. understand the various concepts of the pharmaceutical legislation in India;
   c. know the various parameters in the Drug and Cosmetic Act and rules;
   d. know the Drug policy, DPCO, Patent and design act;
   e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
   f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
   g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

2. Course Outcomes:

1. Apply practice the Professional ethics; Comprehend various Indian Pharmaceutical Acts and Laws
2. Understand the various concepts of the pharmaceutical legislation in India and their implications in the development and marketing of pharmaceuticals
3. Know the various parameters in the Drug and Cosmetic Act and rules and Prioritize other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.
4. Remember the Drug policy, DPCO, Patent and design act
5. Understand the labeling requirements and packaging guidelines for drugs and cosmetics;
6. Be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act

Text books (Theory)

Mithal, B M. Textbook of Forensic Pharmacy. Calcutta: National; 1988.

Reference books (Theory)

a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
c. Reports of the Pharmaceutical Enquiry Committee
d. I.D.M.A., Mumbai. DPCO 1995
e. Various reports of Amendments.
f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
g. Eastern Book Company. The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3.Detailed syllabus and lecture wise schedule: Title of the topic

1. **Pharmaceutical Legislations** – A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.**

   Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.

   Sales, Import, labeling and packaging of Drugs and Cosmetics Provisions Relating to Indigenous Systems.

   Constitution and Functions of DTAB,DCC,CDL. Qualification and duties –Govt. analyst and Drugs Inspector.
4. **Pharmacy Act –1948.**

   Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**

   Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price Control Order & National Drug Policy (Current).**
10. **Prevention of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes:

1. To understand the chemistry of drugs with respect to their biological activity
2. To know the metabolism, adverse effect, and therapeutic activity of drugs.
3. To understand the different modern techniques of drug design & describe the mechanism actions of categories of drugs
4. To relate influence of substituents on the physico-chemical properties and biological activity of drugs SAR of all classes of drugs.
5. Explain the therapeutic uses and adverse reactions of drugs belonging to different classes for the benefit of society
6. Write the routes of synthesis of drugs & sketch the Structures.

Course Content

1. **Modern concept of rational drug design:** A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. **Anti-infective agents**

a) Local anti-infective agents
b) Preservatives
c) Antifungal agents
d) Urinary tract anti-infectives
e) Antitubercular agents
f) Antiviral agents and Anti AIDS agents
g) Antiprotozoal agents
h) Anthelmentics
i) Antiscabies and Antipedicular agents

3. Sulphonamides and sulphones

4. Antimalarials

5. Antibiotics

6. Antineoplastic agents

7. Cardiovascular agents

a) Antihypertensive agents
b) Antianginal agents and vasodilators
c) Antiarrhythmic agents
d) Antihyperlipidemic agents
e) Coagulants and Anticoagulants
f) Endocrine

8. Hypoglycemic agents

9. Thyroid and Antithyroid agents
10. Diureties
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. To understand Nomenclature of simple organic compounds in different classes, make 3D S tereomodels & to apply principles of organic chemistry for synthesis of drugs with emphasis on environment and safety
2. Determination of some important physical properties like melting point, boiling point, solubility, & to learn demonstrate TLC techniques for monitoring reactions and checking purity of synthesized compounds.
3. Use principles of Purification of Organic compounds & qualitative analysis for identification and structural confirmation of synthesized compounds.
4. Able to understand the Synthesis of organic compounds and study about principles, named reactions and mechanisms involved.
5. Compute, analyze and record the observations
6. Evaluate the need of advancements in the therapy of diseases

Course Content

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refra ctivity of compounds for QSAR analysis.

Reference Books:

1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
2. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
3. Burgers, Medicinal Chemistry, M.E.,Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
4. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
5. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
6. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
7. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
8. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
9. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory: 2 Hrs. /Week

1. **Objectives:** Upon completion of the subject student shall be able to (Know, do, appreciate)
   1. understand the principle involved in formulation of various pharmaceutical dosage forms;
   2. prepare various pharmaceutical formulation;
   3. perform evaluation of pharmaceutical dosage forms; and
   4. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

2. **Course Outcomes:**
   1. Understand the principle involved in formulation of various pharmaceutical dosage forms.
   2. Prepare various pharmaceutical formulation.
   3. Justify the composition, containers, labels, expiry period, economy, acceptance drug Products.
   4. Perform evaluation of pharmaceutical dosage forms.
   5. Understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.
   6. Adapt Good Laboratory Practices.

Text books (Theory)

a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
b. Rowlings Text book of Pharmaceutics
c. Tutorial Pharmacy – Cooper &Gun

Reference books (Theory)

a. Remington's Pharmaceutical Sciences
b. USP/BP/IP

3. Detailed syllabus and lecture wise schedule: Title of the topic

1. **Pharmaceutical dosage form- concept and classification**
2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. Parenterals Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization

6. Ophthalmic preparations (Semi – Solids): Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
7. Definition and concept of Controlled and novel Drug delivery systems with available examples, viz. parentral, trans dermal, buccal, rectal, nasal, implants, ocular

3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Review of marketed drug products of various dosage forms.
2. Justify the composition, containers, labels, expiry period, economy, acceptance drug Products.
3. Formulate solid, liquid, semisolid, parenteral pharmaceuticals and cosmetics.
4. Select appropriate manufacturing equipment's.
5. Evaluate quality of pharmaceuticals and cosmetics.
6. Adapt Good Laboratory Practices.

List of Experiments:

1. **Manufacture of Tablets**
    a. Ordinary compressed tablet-wet granulation
    b. Tablets prepared by direct compression.
    c. Soluble tablet.
    d. Chewable tablet.
2. **Formulation and filling of hard gelatin capsules**
3. **Manufacture of parenterals**
    a. Ascorbic acid injection
    b. Calcium gluconate injection
    c. Sodium chloride infusion.
    d. Dextrose and Sodium chloride injection/ infusion.

4 Evaluation of Pharmaceutical formulations (QC tests)

a. Tablets
b. Capsules
c. Injections

5. **Formulation of two liquid oral preparations and evaluation by assay**
    a. Solution: Paracetamol Syrup
    b. Antacid suspensions- Aluminum hydroxide gel
6. **Formulation of semisolids and evaluation by assay**
    a. Salicyclic acid and benzoic acid ointment
    b. Gel formulation Diclofenac gel
7. **Cosmetic preparations**
    a. Lipsticks
    b. Cold cream and vanishing cream
    c. Clear liquid shampoo
    d. Tooth paste and tooth powders.

8. **Tablet coating (demonstration)**

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives:** At completion of this subject it is expected that students will be able to understand –

    a. the pathophysiology of selected disease states and the rationale for drug therapy;
    b. the therapeutic approach to management of these diseases;
    c. the controversies in drug therapy;
    d. the importance of preparation of individualised therapeutic plans based on diagnosis;
    e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
    f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
    g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
    h. to discuss the controversies in drug therapy;
    i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
    j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

2. **Course Outcomes:**
    1. Describe the pathophysiology of diseases and the rationale for drug therapy.
    2. Illustrate the therapeutic approach to management of the diseases.
    3. Demonstrate the controversies in drug therapy.
    4. Sketch the individualized therapeutic plan based on diagnosis of patient.
    5. Design patient's specific parameters relevant in initiating drug therapy and monitoring drug therapy.
    6. Summarize the therapeutic approach to management of the diseases with reference to latest available evidences.

Course Content

1. **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
2. **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
3. **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
4. **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
5. Pain management including Pain pathways, neuralgias, headaches.
   Evidence Based Medicine

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

1. Pathologic basis of disease - Robins SL, W.B.Saunders publication
2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
3. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda – Kimble MA
4. Avery’s Drug Treatment, 4th Edn, 1997, Adis International Limited.
5. Relevant review articles from recent medical and pharmaceutical literature.

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. List the subjective-objective parameters.
2. Review the clinical presentation and diagnosis of disease state.
3. Apply the pharmacotherapeutic principles in disease management.
4. Prepare pharmaceutical care plan.
5. Revise the pharmaceutical care plan as per pharmacotherapy problems.
6. Recommend the monitoring parameters and outcome measures.

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Course Content

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

1. **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
2. **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
3. **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
4. **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
5. Pain management including Pain pathways, neuralgias, headaches.
6. Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year

4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2 HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

1. **Objectives:** Upon completion of the course, the student shall be able to –
    a. know various drug distribution methods;
    b. know the professional practice management skills in hospital pharmacies;
    c. provide unbiased drug information to the doctors;
    d. know the manufacturing practices of various formulations in hospital set up;
    e. appreciate the practice based research methods; and
    f. appreciate the stores management and inventory control.

2. **Course Outcomes:**
    1. Describe the stores management and inventory control.
    2. Recognize and explain roles and responsibilities of hospital pharmacist.
    3. Prepare and practice therapeutic guidelines and hospital formulary.
    4. Illustrate and employ various drug distribution methods in hospital.
    5. Design and develop central sterile supply services.
    6. Describe distribution of Narcotic and other controlled substances.

Text books: (latest editions)

a. Hospital pharmacy by William.E. Hassan
b. A text book of Hospital Pharmacyby S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

a. WHO consultative group report.
b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. **Lecture wise programme**:

Topics

1. 1Hospital - its Organisation and functions
2. Hospital pharmacy-Organisation and management
    a) Organizational structure-Staff, Infrastructure & work load statistics
    b) Management of materials and finance
    c) Roles & responsibilities of hospital pharmacist
3. The Budget – Preparation and implementation
4. Hospital drug policy
    a) Pharmacy and Therapeutic committee (PTC)
    b) Hospital formulary
    c) Hospital committees -Infection committee-Research and ethical committee
    d) developing therapeutic guidelines

e) Hospital pharmacy communication - Newsletter

5. Hospital pharmacy services
   a) Procurement & warehousing of drugs and Pharmaceuticals
   b) Inventory control Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock
   c) Drug distribution in the hospital
      i. Individual prescription method
      ii. Floor stock method
      iii. Unit dose drug distribution method
   d) Distribution of Narcotic and other controlled substances
   e) Central sterile supply services – Role of pharmacist

6. Manufacture of Pharmaceutical preparations
   a) Sterile formulations – large and small volume parenterals
   b) Manufacture of Ointments, Liquids, and creams
   c) Manufacturing of Tablets, granules, capsules, and powders
   d) Total parenteral nutrition

7. Continuing professional development programs Education and training
8. Radio Pharmaceuticals – Handling and packaging
9. Professional Relations and practices of hospital pharmacist

4.2 HOSPITAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Describe inventory control.
2. Review and summarise unbiased drug information.
3. Solve drug information queries using various tools.
4. Categorise various drug interactions.
5. Design and develop hospital formulary.
6. Evaluate the prescription for various drug interactions.

Course Content

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3 CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

1. Objectives:

Upon completion of the subject student shall be able to (Know, do, appreciate) –

a. monitor drug therapy of patient through medication chart review and clinical review;
b. obtain medication history interview and counsel the patients;
c. identify and resolve drug related problems;
d. detect, assess and monitor adverse drug reaction;
e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
f. retrieve, analyse, interpret and formulate drug or medicine information.

2. Course Outcomes:

1. Identify drug related problems in patient therapy through monitoring of drug therapy, medication chart review and clinical review.
2. Interpret laboratory results (as monitoring parameters in therapeutics) of diseases.
3. Prepare relevant drug or medicine information and counsel the patients.
4. Solve and manage Adverse Drug Reactions.
5. Formulate evidence-based drug information for better practices to be followed by physicians.
6. Justify and appraise quality assurance of clinical pharmacy services.

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

3. **Detailed syllabus and lecture wise schedule: Title of the topic**

    1. **Definitions, development and scope of clinical pharmacy**
    2. **Introduction to daily activities of a clinical pharmacist**
        a) Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
        b) Ward round participation
        c) Adverse drug reaction management
        d) Drug information and poisons information
        e) Medication history
        f) Patient counseling
        g) Drug utilisation evaluation (DUE) and review (DUR)
        h) Quality assurance of clinical pharmacy services

3. **Patient data analysis**

    The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.

4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
    a. Haematological, Liver function, Renal function, thyroid function tests
    b. Tests associated with cardiac disorders
    c. Fluid and electrolyte balance
    d. Microbiological culture sensitivity tests
    e. Pulmonary Function Tests
5. **Drug & Poison information**
    a. Introduction to drug information resources available
    b. Systematic approach in answering DI queries
    c. Critical evaluation of drug information and literature
    d. Preparation of written and verbal reports
    e. Establishing a Drug Information Centre
    f. Poisons information- organization & information resources
6. **Pharmacovigilance**
    a. Scope, definition and aims of pharmacovigilance
    b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
    c. Reporting, evaluation, monitoring, preventing & management of ADRs
    d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Identify clinically significant data from the medical case files.
2. Relate the clinically significant data with patients medical condition.
3. Compare the patient's subjective and objective data to interpret diagnosis.
4. Practice drug and poison information services.
5. Assess adverse drug reactions, and medication errors.
6. Recommend suitable drug therapy changes for best possible patient outcomes.

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

a. Answering drug information questions (4 Nos)
b. Patient medication counselling (4 Nos)
c. Case studies related to laboratory investigations (4 Nos)
d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

Course Outcomes:

1. Define the clinical study design.
2. Describe suitable research methodology.
3. Compute sample size for research study.
4. Categorise the data for variable correlation.
5. Analyse the data for statistical means.
6. Conclude the study results.

1. Detailed syllabus and lecture wise schedule

1. Research Methodology

a) Types of clinical study designs: Case studies, observational studies, interventional studies,
b) Designing the methodology
c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
d) Report writing and presentation of data

2. Biostatistics

2.1 a) Introduction
b) Types of data distribution
c) Measures describing the central tendency distributions- average, median, mode
d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 Data graphics

Construction and labelling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots

2.3 Basics of testing hypothesis

a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
b) Level of significance (Parametric data)- student's test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one-way ANOVA)
d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.
e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system

Drug Information Retrieval & Storage:

Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval

Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes:

1. Understand the concept of absorption, distribution, metabolism and excretion of drug.
2. Calculate pharmacokinetic parameters of drugs.
3. Implement effective compartmental modelling in pharmacokinetic studies
4. Define multiple dosage regimen for effective therapeutic action
5. Design bioavailability-bioequivalence study protocol to establish the quality of generic drugs.
6. Explore application of linear and non-linear pharmacokinetic principles

Course Content

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
   a. Absorption of drugs from gastrointestinal tract.
   b. Drug Distribution.
   c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
   a. Mathematical model
   b. Drug levels in blood.
   c. Pharmacokinetic model
   d. Compartment models
   e. Pharmacokinetic study.

3. One compartment open model.
   a. Intravenous Injection (Bolus)
   b. Intravenous infusion.

4. Multiompartment models.
   a. Two compartment open model.
   b. IV bolus, IV infusion and oral administration

5. Multiple – Dosage Regimens.
   a. Repititive Intravenous injections – One Compartment Open Model
   b. Repititive Extravascular dosing – One Compartment Open model
   c. Multiple Dose Regimen – Two Compartment Open Model

6. Nonlinear Pharmacokinetics.
   a. Introduction
   b. Factors causing Non-linearity.
   c. Michaelis-menton method of estimating parameters.

7. Noncompartmental Pharmacokinetics.
   a. Statistical Moment Theory.
   b. MRT for various compartment models.
   c. Physiological Pharmacokinetic model.

8. Bioavailability and Bioequivalence.

a. Introduction.
b. Bioavailability study protocol.
c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Improve dissolution and solubility characteristics of slightly soluble drugs
2. Understand the effect of time and concentration of drug on plasma-protein binding
3. Determine elimination half-life, pharmacokinetic parameters using given urinary excretion data
4. Execute absorption studies in animal intestine
5. Design bioavailability-bioequivalence study protocol to establish the quality of generic drugs.
6. Compute, analyze various pharmacokinetic parameters using blood plasma data

Course Content

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of Ka, Ke, t1/2, Cmax, AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed. (eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on Content time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
c. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
f. Biopharmaceutics; By Swarbrick
g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

Course Outcomes:

1. Describe general principles involved in the management of poisoning.
2. Identify and locate clinical symptoms of acute poisoning.
3. Relate the type of poisoning and practice various antidotes.
4. Categorise the venomous snake bites and type of toxins based upon clinical symptoms.
5. Explain treatment of substance abuse and dependence.
6. Evaluate and explain toxicokinetics.

Course Content

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents

    a. Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
    b. Opiates overdose.
    c. Antidepressants
    d. Barbiturates and benzodiazepines.
    e. Alcohol: ethanol, methanol.
    f. Paracetamol and salicylates.
    g. Non-steroidal anti-inflammatory drugs.
    h. Hydrocarbons: Petroleum products and PEG.
    i. Caustics: inorganic acids and alkali.
    j. Radiation poisoning

8. Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

a) CNS stimulants: amphetamine
b) Opioids
c) CNS depressants
d) Hallucinogens: LSD
e) Cannabis group
f) Tobacco

References:

a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad.

Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes:

1. Define various approaches to drug discovery.
2. Describe good clinical practices.
3. Practice ethical considerations in clinical research.
4. Compare regulatory environments in USA, Europe, and India.
5. Design clinical study documents.
6. Evaluate safety monitoring in clinical trials.

Course Content

1. Drug development process: Introduction Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP

    a) Sponsor
    b) Investigators
    c) Clinical research associate
    d) Auditors
    e) Contract research coordinators
    f) Regulatory authority

11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

References:

a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes:

1. Understand and summaries origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.
2. Recognize, interpret, and analyze the measurements of outcomes in pharmacoepidemiology.
3. Compare and contrast typical pharmacoepidemiologic study designs and explain their strengths and weaknesses.
4. Explain, compare, and analyze the features of Ad Hoc data sources and automated data systems for pharmacoepidemiology and pharmacovigilance purposes.
5. Explain and analyze the problems in the special applications of pharmacoepidemiological studies.
6. Identify, classify, compare, analyze, and evaluate the various methods of pharmacoeconomic studies.

Course Content

1.Pharmacoepidemiology:

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. Phrmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. Applications of Pharmacoeconomics Software and case studies

5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs. /Week

Course Outcomes:

1. Identify dose and dosing intervals in all age group patients.
2. Convert intravenous drug administration to oral drug administration.
3. Demonstrate the pharmacokinetics and pharmacodynamics of various drugs.
4. Practice dose adjustments in renal and hepatic impaired patients.
5. Summarize population pharmacokinetic data.
6. Interpret pharmacogenetic and PK-PD relation.

Course Content

1. **Introduction to Clinical pharmacokinetics.**
2. **Design of dosage regimens:**

   Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

3. **Pharmacokinetics of Drug Interaction:**
   a. Pharmacokinetic drug interactions
   b. Inhibition and Induction of Drug metabolism
   c. Inhibition of Biliary Excretion.

4. **Therapeutic Drug monitoring:**
   a. Introduction
   b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
   c. Indications for TDM. Protocol for TDM.
   d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
   e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

5. **Dosage adjustment in Renal and hepatic Disease.**
   a. Renal impairment
   b. Pharmacokinetic considerations
   c. General approach for dosage adjustment in Renal disease.
   d. Measurement of Glomerular Filtration rate and creatinine clearance.
   e. Dosage adjustment for uremic patients.
   f. Extracorporeal removal of drugs.
   g. Effect of Hepatic disease on pharmacokinetics.

6. **Population Pharmacokinetics.**
    a. Introduction to Bayesian Theory.
    b. Adaptive method or Dosing with feed back.
    c. Analysis of Population Pharmacokinetic Data.

7. **Pharmacogenetics**
    a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
    b. Genetic Polymorphism in Drug Transport and Drug Targets.
    c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

APPENDIX-B

(See regulation 9)

CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.
2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -

   a) are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948;
   b) have 300 bedded hospital attached to it.

I. Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

II. Speciality

a) Tertiary care hospitals are desirable
b) Medicine[compulsory], and any three specialization of the following
   1. Surgery
   2. Pediatrics
   3. Gynecology and obstetrics
   4. Psychiatry
   5. Skin and VD
   6. Orthopedics

III. Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

3) TEACHING STAFF REQUIREMENT

i. Staff Pattern: All faculty shall be full time. However, part time perceptors in hospital shall be allowed.

ii. Subject wise specialisation of the Teaching Staff:

S.No.	Subject	Specialisation required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics

17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

iii. Teaching Staff :

Department/Division	**Name of the post**	**No.**
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

iv. Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others:

Sl. No.	**CADRE**	**QUALIFICATIONS**	**EXPERIENCE**
1.	Lecturer	Basic degree in pharmacy (B.Pharm). Registration as a pharmacist under the Pharmacy Act. First Class Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	No minimum requirement.
2.	Assistant Professor	i. Basic degree in pharmacy (B.Pharm). ii. Registration as a pharmacist under the Pharmacy Act. iii. Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv. Ph.D. degree (with First Class degree either at Bachelor's or Master's level) in the appropriate branch of specialization in Pharmacy.	Three years' experience in Teaching or Research at the level of Lecturer or equivalent.

3.	Professor	i. Basic degree in pharmacy (B.Pharm). ii. ii) Registration as a pharmacist under the Pharmacy Act. iii. Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm). iv. Ph.D. degree (with first Class either at Bachelor's or Master's level) in appropriate branch of specialization in Pharmacy.	Ten years' experience in Teaching or Research. Out of which five years must be as Assistant Professor.
4.	Director or Principal or Head of institute	i.Basic degree in pharmacy (B.Pharm). ii.Registration as a pharmacist under the Pharmacy Act. iii.Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv.Ph.D. degree (with first Class degree either at Bachelor's or Master's level in the appropriate branch of specialization in Pharmacy.	i. Fifteen years' experience in Teaching or Research. ii. Out of which five years must be as Professor or above in Pharmacy. iii. Desirable: Administrative experience in responsible position. iv. The maximum age for holding the post shall be 65 years.

Note: If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

IV. Workload of Faculty: Professor – 8 hrs. per week Assistant Professor – 12 hrs. per week Lecturers – 16 hrs. per week

V. Training of Pharmacy Practice Faculty:

a)	Teaching staff will be trained as per the module prescribed by the Central Council.		
b)	Duration of training	–	Minimum 3 months.
c)	Training sites	–	Institutions running pharmacy practice or Programmes for atleast five years.
d)	Trainer	–	Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

4) NON-TEACHING STAFF:

Sl.No.	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm
2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor Degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning personnel	Adequate	---
11	Gardener	Adequate	---

5) ACCOMMODATION:

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores, etc.

At least two lecture halls alongwith eight laboratories as specified below should be provided for: —

1. Pharmaceutics and Pharmacokinetics Lab - 2
2. Life Science (Pharmacology, Physiology, Pathophysiology) - 2
3. Phytochemistry or Pharmaceutical Chemistry - 2
4. Pharmacy Practice - 2

Total = 8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS:

Department wise list of minimum equipment's

A. DEPARTMENT OF PHARMACOLOGY:

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01
5	Spygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone
11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01
15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10
20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01

30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

B. DEPARTMENT OF PHARMACOGNOSY:

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02
4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi	02
	channeled)	
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY:

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10
6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06
8	Muffle Furnace	01
9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Distillation Unit	02
2	Reflux flask and condenser single necked	20
3	Reflux flask and condenser double/ triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nesslers Cylinders	40

Note:

D. DEPARTMENT OF PHARMACEUTICS:

I. Equipment:

S.No	Name	Minimum required Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01
20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1liter capacity with speed control	05 EACH10
30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02

37	Conical Percolator (glass/copper/ stainless steel)	10
38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium,	05 each
	large)	
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department**.**

E. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY:

S.No.	Name	Minimum required Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01

16	Paper Electrophoresis Unit	01
17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

F. DEPARTMENT OF PHARMACY PRACTICE: Equipment:

S.No.	Name	Minimum required Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1
10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

1. Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.

2. Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and the department.

G. CENTRAL INSTRUMENTATION ROOM:

S.No.	Name	Minimum required Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Flourimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra-Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

APPENDIX-C

(See regulation 16)

INTERNSHIP

7. SPECIFIC OBJECTIVES:

(i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.

(ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.

(iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.

(iv) to demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.

(v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.

(vi) to communicate effectively with patients and the community.

8. OTHER DETAILS:

i. All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.

ii. Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

iii. Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a

period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

9. ASSESSMENT OF INTERNSHIP:

i. The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.

ii. Satisfactory completion of internship shall be determined on the basis of the following: -

(1) Proficiency of knowledge required for each case management SCORE 0-5

(2) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5

(3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5

(4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5

(5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

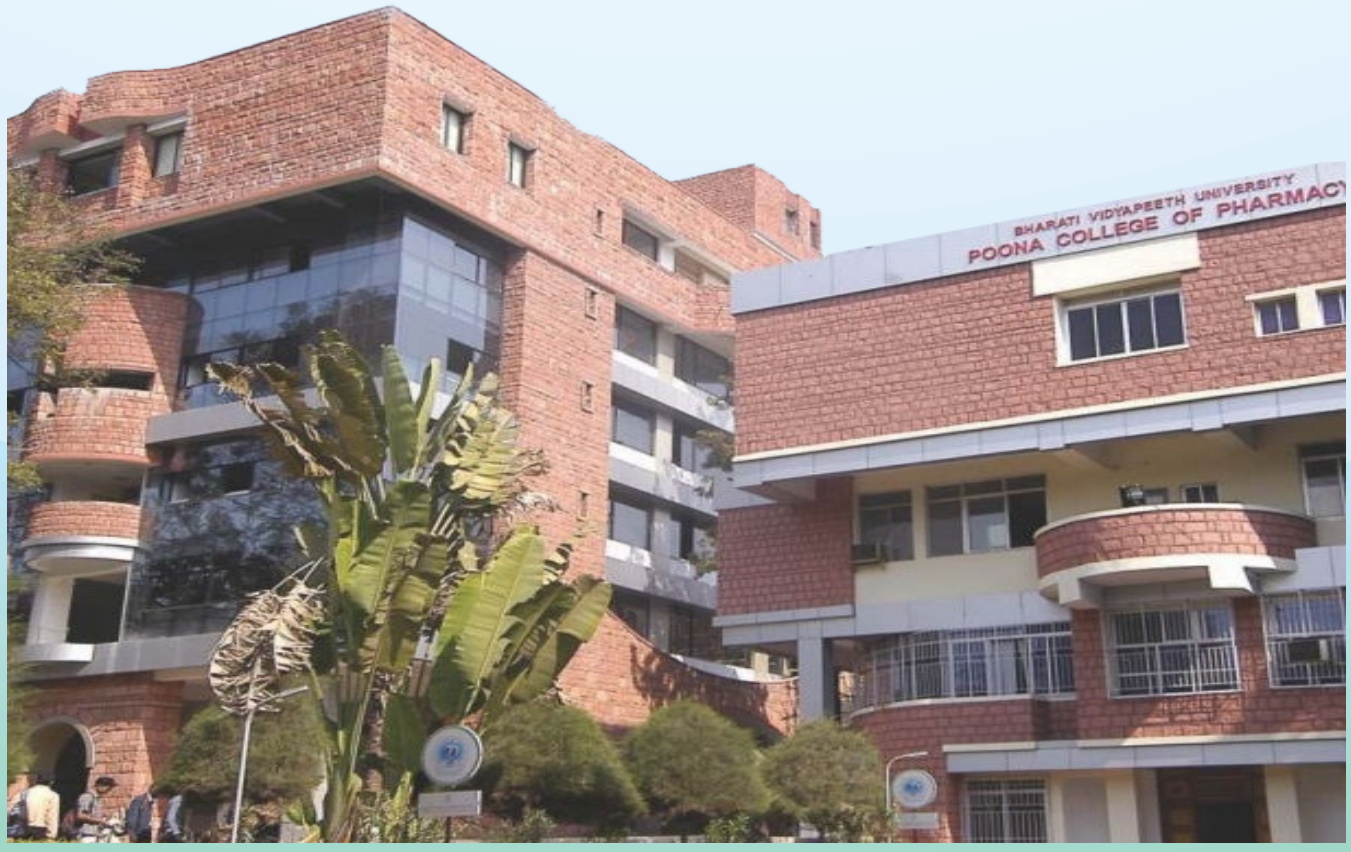
APPENDIX-D

(See regulation 17)

CONDITIONS TO BE FULFILLED BY THE EXAMINING AUTHORITY

1. The Examining Authority shall be a statutory Indian University constituted by the Central Government/State Government/Union Territory Administration. It shall ensure that discipline and decorum of the examinations are strictly observed at the examination centers.
2. It shall permit the Inspector or Inspectors of the Pharmacy Council of India to visit and inspect the examinations.
3. It shall provide:-
   (a) adequate rooms with necessary furniture for holding written examinations;
   (b) well-equipped laboratories for holding practical examinations;
   (c) an adequate number of qualified and responsible examiners and staff to conduct and invigilate the examinations; and
   (d) such other facilities as may be necessary for efficient and proper conduct of examinations.
4. It shall, if so required by a candidate, furnish the statement of marks secured by a candidate in the examinations after payment of prescribed fee, if any, to the Examining Authority.
5. It shall appoint examiners whose qualifications should be similar to those of the teachers in the respective subjects as shown in Appendix–B.
6. In pursuance of sub–section (3) of section 12 of the Pharmacy Act, 1948, the Examining Authority shall communicate to the Secretary, Pharmacy Council of India, not less than six weeks in advance the dates fixed for examinations, the time-table for such examinations, so as to enable the Council to arrange for inspection of the examinations.
7. The Examining Authority shall ensure that examiners for conducting examination for Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be persons possessing pharmacy qualification and are actually involved in the teaching of the Pharm.D. and Pharm.D. (Post Baccalaureate) programmes in an approved institution.

(ARCHNA MUDGAL)
Registrar-cum-Secretary
Pharmacy Council of India
New Delhi – 110002



Bharati Vidyapeeth
(Deemed to be University) Pune, India
Poona College of Pharmacy
Erandwane, Pune - 411 038
Website: https://www.bvuniversity.edu.in/pcp
Email: pcp@bharatividyapeeth.edu

BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE

Faculty of Pharmaceutical Sciences
Doctor of Pharmacy
Pharm D.
Old Syllabus

BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY)

'A' GRADE AWARDED BY GOVT OF INDIA
'A+' GRADE REACCREDITATION BY NAAC

Faculty of Pharmaceutical Sciences
Doctor of Pharmacy

Pharm D.

PROGRAMME STRUCTURE & SYLLABUS

w.e.f. 2022-23
Pharm D. 2022-23 (PCI Syllabus)

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
'A' GRADE AWARDED BY GOVT OF INDIA
'A+' GRADE REACCREDITATION BY NAAC

FACULTY OF PHARMACEUTICAL SCIENCES

Pharm D.

Programme Structure and Syllabus

w.e.f. 2022-23
Pharm D. 2022-23 (PCI Syllabus)

Bharati Vidyapeeth (Deemed to be University), Pune

Bharati Vidyapeeth, the parent organization of this University is one of the largest educational organizations in the country. It has 180 educational units under its umbrella including 80 Colleges and Institutes of conventional and professional disciplines.

The Ministry of Human Resource Development, Government of India on the recommendations of the University Grants Commission accorded the status of "Deemed to be University" initially to a cluster of 12 units of Bharati Vidyapeeth. Subsequently, 17 additional colleges / institutes were brought within the ambit of Bharati Vidyapeeth University wide various notifications of the Government of India. Bharati Vidyapeeth (Deemed to be University) commenced its functioning on 26th April, 1996.

Constituent Units of Bharati Vidyapeeth (Deemed to be University)

1. BVDU Medical College, Pune.
2. BVDU Dental College & Hospital, Pune
3. BVDU College of Ayurved, Pune
4. BVDU Homoeopathic Medical College, Pune
5. BVDU College of Nursing, Pune
6. BVDU Yashwantrao Mohite College of Arts, Science & Commerce, Pune.
7. BVDU New Law College, Pune
8. BVDU Social Sciences Centre (M.S.W.), Pune
9. BVDU Yashwantrao Chavan Institute of Social Science Studies & Research, Pune.
10. BVDU Centre for Research & Development in Pharmaceutical Sciences & Applied Chemistry, Pune
11. BVDU College of Physical Education, Pune.
12. BVDU Institute of Environment Education & Research, Pune
13. BVDU Institute of Management & Entrepreneurship Development, Pune
14. BVDU Poona College of Pharmacy, Pune
15. BVDU College of Engineering, Pune
16. BVDU Interactive Research School in Health Affairs (IRSHA), Pune
17. BVDU Rajiv Gandhi Institute of Information Technology & Biotechnology, Pune
18. BVDU College of Architecture, Pune
19. BVDU Abhijit Kadam Institute of Management & Social Sciences, Solapur
20. BVDU Institute of Management, Kolhapur
21. BVDU Institute of Management & Rural Development administration, Sangli
22. BVDU Institute of Management & Research, New Delhi
23. BVDU Institute of Hotel Management & Catering Technology, Pune
24. BVDU Yashwantrao Mohite Institute of Management, Malakapur-Karad
25. BVDU Medical College & Hospital, Sangli
26. BVDU Dental College & Hospital, Mumbai
27. BVDU Dental College & Hospital, Sangli
28. BVDU College of Nursing, Sangli
29. BVDU College of Nursing, Navi Mumbai

The status of university was given to a cluster of these colleges and institutes in appreciation of the high level of their academic excellence and for their potential for further growth.

During the last 20 years or so, the University has achieved higher pinnacles of academic excellence and has established its reputation to such an extent that it attracts students not only from various parts of India but also from abroad. According to a survey conducted by Association of Indian Universities, this University is one among the top ten Universities in the country preferred by the overseas students for admissions. At present, there are more than 850 overseas students from 47 countries on the rolls of constituent units of this University.

During the last 20 years, there has been tremendous academic expansion of the University. It now conducts in all 305 courses in its constituent units, of them 108 are Post Graduate, 45 are Under Graduate and 55 Diploma level courses. 12 Fellowship and 5 certificate courses. All the professional courses which the University conducts such as those of Medicine, Dentistry, Engineering etc., have approval of the respective statutory councils, viz., Medical Council of India, Dental Council of India, All India Council for Technical Education etc.

The University is a throbbing center of research activities and has launched Ph.D. programmes in 77 subjects and M.Phil in 3 subjects. It has also introduced quite few innovative academic programmes such as Masters in Clinical Optometry, M.Tech. in Nano Technology etc.

The University's performance and achievements were assessed by the "National Assessment and Accreditation Council" and it was reaccredited with a prestigious "A" grade in 2011. Some programmes of the constituent units such as College of Engineering at Pune, Management Institute in Delhi and others have also been accredited by "National Board of Accreditation". Three constituent units of Bharati Vidyapeeth (Deemed to be University) are also the recipients of ISO 9001-2001 certifications.

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
POONA COLLGE OF PHARMACY, PUNE

Bharati Vidyapeeth's Poona College of Pharmacy was established in 1981. This college has got approval and recognition of All India Council of Technical Education, New Delhi, Pharmacy Council of India, New Delhi and Bharati Vidyapeeth (Deemed to be University). Earlier the college was affiliated to University of Poona and Maharashtra University of Health Sciences. Now it is a constituent unit of Bharati Vidyapeeth (Deemed to be University). The College conducts B.Pharm, M.Pharm (in Pharmaceutics, Pharm. Chemistry, Pharmacology, Pharmacognosy and Quality Assurance Techniques). The college is housed in beautiful building and located in our bewitching teaching complex at Erandwane, Paud Road, Pune. The excellence which this college has achieved during these years in Pharmacy education is mainly due to its experienced and qualified teaching faculty and the infrastructural facilities of high quality provided in the college. The college has excellent library with modern books on pharmacy. The college also provides hostel facilities on a limited scale to our students both boys and girls.

As soon as the college came under the ambit of Bharati Vidyapeeth (Deemed to be University), the syllabus of B.Pharm and M.Pharm Course was revised and upgraded with the help of eminent experts in the pharmacy and the same was approved by University Authorities. While doing so the guidelines given by UGC, AICTE, Pharmacy Council of India, and the societal needs have been taken into consideration.

VISION:

To be recognized as a premier pharmacy institution of academic excellence.

MISSION STATEMENT:

1) To produce competent pharmacists catering to the needs of Industry, Academia, Research and Society.
2) To create a centre of excellence for education and research in the field of pharmacutical sciences.
3) To contribute our humble share to ensure the well-being and to reduce the suffering of mankind.

PROGRAMME EDUCATIONAL OBJECTIVES (PEO)

1) To provide a comprehensive pharmaceutical education leading to B. Pharm. Degree.
2) To integrate pharmacy knowledge and skills with pharmaceutical research so as to increase inclination for higher studies and research.
3) To develop pharmacists to contribute effectively in the social health care system.
4) To provide hands on training through state of art infrastructure to meet challenges of pharmacy profession.
5) To inculcate leadership and entrepreneurship capabilities in future pharmacists.

PROGRAMME OUTCOMES (POS)

On completion of the B. Pharm. programme, a student will be able to:

1. Demonstrate knowledge of the basic pharmaceutical sciences and the ability to acquire, manage and use current information for problem solving.
2. Describe the synthesis, formulation, analysis and pharmacological aspects of drugs and pharmaceuticals.
3. Identify the rules and regulations involved in the drug discovery and development, manufacture, distribution and sale of medicines.
4. Observe record, analyze, criticize, organize, improvise and manage documents, data and information related to pharmaceutical products and practices.
5. Develop problem-based learning approach and analytical thinking in his/her academic and professional life.
6. Demonstrate the ability to plan and implement professional activities.
7. Act efficiently as a leader in the diverse areas of the profession.
8. Write, interpret and communicate effectively and scientifically.
9. Apply the knowledge and skills gained through education to gain recognition in professional circle and society.
10. Partnering with other health care communities to provide innovative solutions.
11. Create awareness in society about the effective and safe use of medicines.
12. Demonstrate eco-friendly products and processes to maintain public health.
13. Imbibe ethical practices and moral values in personal and professional endeavors.
14. Tackle future challenges through lifelong learning.

[PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and Family Welfare

(Pharmacy Council of India)

New Delhi, 10th May, 2008.

Pharm.D. Regulations 2008

Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948).

(As approved by the Government No.V.13013/1/2007-PMS, dated the 13th Council of India). of India, Ministry of Health vide, letter March, 2008 and notified by the Pharmacy No.14-126/2007-PCI. — In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations, namely: -

CHAPTER-I

1) Short title and commencement. –
    a. These regulations may be called the Pharm.D. Regulations 2008.
    b. They shall come into force from the date of their publication in the official Gazette.
2) Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

CHAPTER-II

3.Duration of the course. –

a) Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

Phase I– consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.

b) Pharm.D. (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one-year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I– consisting of First and Second academic year.

Phase II – consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.

4. Minimum qualification for admission to. –

a) Pharm.D. Part-I Course – A pass in any of the following examinations -

1. 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects:
2. Mathematics or Biology.
    a. A pass in D.Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.
    b. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

b) Pharm.D. (Post Baccalaureate) Course -

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –

(i) Pharm.D. Programme – 30 students.

(ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.

6. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.

7. Course of study. – The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

T A B L E S

First Year:

S.No.	**Name of Subject**	**No. of hours of Theory**	**No. of hours of Practical**	**No. of hours of Tutorial**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	**16**	**18**	**6 = (40)**

* For Biology

Second Year:

S.No	**Name of Subject**	**No. of hours of Theory**	**No. of hours of Practical**	**No. of hours of Tutorial**
(1)	**(2)**	**(3)**	**(4)**	**(5)**
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	**17**	**9**	**6 = 32**

Third Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	**16**	**15**	**5 = 36**

Fourth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	**15**	**12**	**6 = 33**

Fifth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours Of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	**8**	**20**	**4 = 32**

* Attending ward rounds on daily basis.

Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

(i) Six months in General Medicine department, and

(ii) Two months each in three other speciality departments

8. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.

9. Approval of the authority conducting the course of study.

(1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.

(2) Any person or pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.

(3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

10. Examination.

(1) Every year there shall be an examination to examine the students.

(2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.

(3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below:

T A B L E S

First Year examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/ Biology	70	30	100	70*	30*	100*
				600			600 = 1200

* for Biology.

Second Year examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			300 = 900

Third Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 100

Fourth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

Fifth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)
70 marks – Thesis work

11. Eligibility for appearing Examination.— Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.

12. Mode of examinations.—

(1) Theory examination shall be of three hours and practical examination shall be of four hours duration.

(2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.

(3) Practical examination shall also consist of a viva –voce (Oral) examination.

(4) Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

13. Award of sessional marks and maintenance of records.—

(1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.

(2) There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.

(3) The sessional marks in practicals shall be allotted on the following basis:-

(i) Actual performance in the sessional examination (20 marks)

(ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10 marks)

14. Minimum marks for passing examination. — A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.

15. Eligibility for promotion to next year. — All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.

16. Internship. — (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.

(2) Every student has to undergo one-year internship as per Appendix-C to these regulations.

17. Approval of examinations. — Examinations mentioned in regulations 10 to12 and 14 shall be held by the examining authority hereinafter referred to as the university, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the examining authority concerned fulfills the conditions as specified in Appendix–D to these regulations.

18. Certificate of passing examination. — Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

CHAPTER-III
Practical training

19. Hospital posting.— Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.

20. Project work. — (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.

(2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

21. Objectives of project work. — The main objectives of the project work is to—

(i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and

(ii) develop the students in data collection, analysis and reporting and interpretation skills.

22. Methodology. — To complete the project work following methodology shall be adopted, namely: —

(i) students shall work in groups of not less than two and not more than four under an authorised teacher;

(ii) project topic shall be approved by the Head of the Department or Head of the Institution;

(iii)project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;

(iv) project work shall be approved by the institutional ethics committee;

(v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and

(vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

23. Reporting .— (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution

(2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.
(3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

24. Evaluation.— The following methodology shall be adopted for evaluating the project work—

(i) Project work shall be evaluated by internal and external examiners.

(ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).

(iii)Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:

	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)

(v) Final evaluation of project work shall be done on the following items:

	Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

APPENDIX-A

(See regulation 8)

PHARM.D. SYLLABUS

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives:**
   a. describe the structure (gross and histology) and functions of various organs of the human body;
   b. describe the various homeostatic mechanisms and their imbalances of various systems;
   c. identify the various tissues and organs of the different systems of the human body;
   d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
   e. appreciate coordinated working pattern of different organs of each system; and
   f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

2. **Course Outcomes:**
   1. Explain the terminologies related to human anatomy and physiology.
   2. Describe the structures, functions, and synchronous working of various systems of human body.
   3. Outline various technologies for evaluating physiological functions.
   4. Summarize the impact of social and environmental factors on body system
   5. Interpret the imbalance of homeostasis responsible for various diseases
   6. Discuss the common disorders prevalent in the society

3. **Course materials: Text books**
   a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.
   b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology.

Publisher: Churchill Livingstone, Edinburg.

Reference books

a. Guyton arthur, C. Physiology of human body. Publisher: Holtsaunders.
b. Chatterjee,C.C. Human physiology. Volume 1&11. Publisher: medical allied agency, Calcutta.
c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
d. Gray's anatomy. Publisher:Churchill Livingstone, London.

4. Lecture wise program: Topics

1. Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)
2. Structure of cell – its components and their functions.
3. Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
4. a) Osseous system - structure, composition and functions of the
   b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

5. Haemopoetic System

a) Composition and functions of blood
b) Haemopoesis and disorders of blood components (definition of disorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation

6. Lymph

a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)

7. Cardiovascular system

a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders

Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

8. Respiratory system

a) Anatomy of respiratory organs and functions
b) Mechanism / physiology of respiration and regulation of respiration
c) Transport of respiratory gases
d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

9. Digestive system

a) Anatomy and physiology of GIT
b) Anatomy and functions of accessory glands of GIT
c) Digestion and absorption
d) Disorders of GIT (definitions only)

10. Nervous system

a) Definition and classification of nervous system
b) Anatomy, physiology and functional areas of cerebrum
c) Anatomy and physiology of cerebellum
d) Anatomy and physiology of mid brain
e) Thalamus, hypothalamus and Basal Ganglia
f) Spinal card: Structure & reflexes – mono-poly-planter
g) Cranial nerves – names and functions
h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

11. Urinary system

a) Anatomy and physiology of urinary system
b) Formation of urine
c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
d) Clearance tests and micturition

12. Endocrine system

a) Pituitary gland
b) Adrenal gland
c) Thyroid and Parathyroid glands
d) Pancreas and gonads

13. Reproductive system

a) Male and female reproductive system
b) Their hormones – Physiology of menstruation
c) Spermatogenesis & Oogenesis
d) Sex determination (genetic basis)
e) Pregnancy and maintenance and parturition
f) Contraceptive devices

14. Sense organs

a) Eye
b) Ear
c) Skin
d) Tongue & Nose

15. Skeletal muscles

a) Histology
b) Physiology of Muscle contraction
c) Physiological properties of skeletal muscle and their disorders (definitions)

16. Sports physiology

a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
c) Drugs and athletics

1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Describe the histology of various tissues.
2. Analyze blood samples for hematological parameters and correlate with clinical conditions.
3. Discuss the anatomy and physiology of various human systems with charts and models.
4. Identify bones and explain their anatomy and physiology.
5. Interpret the physiological feedback mechanisms.
6. Explain the importance of hematological parameters, health and family planning devices to the society.

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
   (a) Epithelial tissue.
   (b) Muscular tissue.
2. Study of tissues of human body
   (a) Connective tissue.
   (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
   (a) Erythrocyte Sedimentation Rate.
   (b) Hemoglobin content of Blood.
   (c) Bleeding time & Clotting time.
8. Determination of
   (a) Blood Pressure.

(b) Blood group.

9. Study of various systems with the help of charts, models & specimens
   (a) Skeleton system part I-axial skeleton.
   (b) Skeleton system part II- appendicular skeleton.
   (c) Cardiovascular system.
   (d) Respiratory system.
   (e) Digestive system.
   (f) Urinary system.
   (g) Nervous system.
   (h) Special senses.
   (i) Reproductive system.
10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastroenemius sciatic nerve preparation
14. To record simple summation curve using gastroenemius sciatic nerve preparation.
15. To record simple effect of temperature using gastroenemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastroenemius sciatic nerve preparation.
17. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for egularity, promptness, viva-voce and record maintenance).

1.2 PHARMACEUTICS (THEORY)

Practical : 3 Hrs./Week

1. **Objectives**: Upon the completion of the course the student should be able to:
   a. know the formulation aspects of different dosage forms;
   b. do different pharmaceutical caluculation involved in formulation;
   c. formulate different types of dosage forms; and
   d. appreciate the importance of good formulation for effectiveness.

2. **Course Outcomes:**
   i. Evaluate the prescription for rational drug therapy
   ii. Explain principles of modern dispensing practices
   iii. Recommend patients about pharmaceutical dosage forms
   iv. Compound and dispense dosage forms
   v. Practice ethics in community pharmacy
   vi. Apply basic principles and calculations in formulation development

3. **Course materials: Text bookk**
   a. Cooper and Gunns Dispensing for pharmacy students.
   b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

   c. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
   d. Remington's Pharmaceutical Sciences.
   e. Register of General Pharmacy by Cooper and Gunn.
   f. General Pharmacy by M.L.Schroff.

4. **Lecture wise programme: Topics**

1 a. Introduction to dosage forms - classification and definitions
   b. Prescription: definition, parts and handling
   c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.

2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.

3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.

4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.

5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.

6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.

8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.

9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

10 Pharmaceutical calculations.

11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.

12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1.2 PHARMACEUTICS (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Understanding the basic knowledge in the formulation aspects of different dosage forms.
2. Formulate the different dosage forms such as solid and liquid orals
3. Recommend patients about pharmaceutical dosage forms and Create patient counselling aids
4. Apply knowledge in formulating various pharmaceutical dosage forms.
5. Practice ethics in community pharmacy
6. Use of practical knowledge in the field of incompatibility and method to overcome

List of Experiments:

1. **Syrups**
   a. Simple Syrup I.P
   b. Syrup of Ephedrine Hcl NF
   c. Syrup Vasaka IP
   d. Syrup of ferrous Phosphate IP
   e. Orange Syrup

2. **Elixir**
   a. Piperizine citrate elixir BP
   b. Cascara elixir BPC
   c. Paracetamol elixir BPC

3. **Linctus**
   a. Simple Linctus BPC
   b. Pediatric simple Linctus BPC

4. **Solutions**
   a. Solution of cresol with soap IP
   b. Strong solution of ferric chloride BPC
   c. Aqueous Iodine Solution IP
   d. Strong solution of Iodine IP
   e. Strong solution of ammonium acetate IP

5. **Liniments**
   a. Liniment of turpentine IP*
   b. Liniment of camphor IP

6. **Suspensions***
   a. Calamine lotion
   b. Magnesium Hydroxide mixture BP

7. **Emulsions***
    a. Cod liver oil emulsion
    b. Liquid paraffin emulsion

8. **Powders***
    a. Eutectic powder
    b. Explosive powder
    c. Dusting powder
    d. Insufflations

9. **Suppositories***
    a. Boric acid suppositories
    b. Chloral suppositories

10. **Incompatibilities**
    c. Mixtures with Physical
    d. Chemical & Therapeutic incompatibilities

*colourless bottles required for dispensing Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives of the Subject** (Know, do, appreciate):

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
e. do the qualitative analysis and determination of biomolecules in the body fluids.

2. **Course Outcomes:**

1. Gain insights into the catalytic functions of enzymes and recognize the significance of isoenzymes in the diagnosis of various diseases.
2. Comprehend the metabolic processes of biomolecules in both normal physiological states and during the manifestation of metabolic disorders.
3. DNA replication, mutation processes, and mechanisms for DNA repair.
4. Know the biochemical principles of organ function tests of kidney, liver and endocrine gland
5. Perform qualitative analysis and determine the presence of biomolecules in body fluids.
6. Understand the principle for performing various biochemical assays

Text books (Theory)

a. Harpers review of biochemistry - Martin
b. Text book of biochemistry – D.Satyanarayana
c. Text book of clinical chemistry- Alex kaplan &Laverve L.Szabo

Reference books (Theory)

a. Principles of biochemistry -- Lehninger
b. Text book of biochemistry -- Ramarao
c. Practical Biochemistry-David T.Plummer.
d. Practical Biochemistry-Pattabhiraman.

3. **Lecture wise programme:**

Topics

1 Introduction to biochemistry: Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.

2 Enzymes: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.

3 Carbohydrate metabolism: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

4 Lipid metabolism: Oxidation of saturated (□-oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea).

5 Biological oxidation: Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;

6 Protein and amino acid metabolism: protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.

7 Nucleic acid metabolism: Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.

8 Introduction to clinical chemistry: Cell; composition; malfunction; Roll of the clinical chemistry laboratory.

9 The kidney function tests: Role of kidney; Laboratory tests for normal function includes-

   a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
   b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
   c) Urine concentration test
   d) Urinary tract calculi. (stones)

10 Liver function tests: Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.

   a) Test for hepatic dysfunction-Bile pigments metabolism.
   b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
   c) Dye tests of excretory function.
   d) Tests based upon abnormalities of serum proteins.

11 Lipid profile tests: Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

12 Immunochemical techniques for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases. Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

13 Electrolytes: Body water, compartments, water balance, and electrolyte distrubution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Course Outcomes:

1. Identification of Urinary constituents and Abnormalities for clinical diagnostics
2. Application of Quantitative Techniques in laboratory tests.
3. Conduct Serum Biochemical Analysis.
4. Explore Enzyme Activity and the factors affecting it.
5. Precision in the preparation of Solutions and reagents useful in clinical testing.
6. Utilize Specialized Diagnostic Techniques in diagnostics.

Title of the Experiment:

1. Qualitative analysis of normal constituents of urine.*
2. Qualitative analysis of abnormal constituents of urine.*
3. Quantitative estimation of urine sugar by Benedict's reagent method.**
4. Quantitative estimation of urine chlorides by Volhard's method.**
5. Quantitative estimation of urine creatinine by Jaffe's method.**
6. Quantitative estimation of urine calcium by precipitation method.**
7. Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
8. Preparation of Folin Wu filtrate from blood.*
9. Quantitative estimation of blood creatinine.**
10. Quantitative estimation of blood sugar Folin-Wu tube method.**
11. Estimation of SGOT in serum.**
12. Estimation of SGPT in serum.**
13. Estimation of Urea in Serum.**
14. Estimation of Proteins in Serum.**
15. Determination of serum bilirubin**
16. Determination of Glucose by means of Glucoseoxidase.**
17. Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
18. Study of factors affecting Enzyme activity. (pH & Temp.)**
19. Preparation of standard buffer solutions and its pH measurements (any two)*
20. Experiment on lipid profile tests**
21. Determination of sodium,calcium and potassium in serum.**

** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives:**
   a. This course is designed to impart a very good knowledge about a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
   b. Some important physical properties of organic compounds;
   c. Free radical/ nucleophyllic [alkyl/ acyl/ aryl] /electrophyllic substitution, free radical/ nucleophyllic / electrophyllic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
   d. Some named organic reactions with mechanisms; and
   e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. Course Outcomes:

1. Understand the principles and procedures of synthesis of drugs
2. Explain need and basic principle and applications of different chemical synthesis and methods thereof.
3. Have knowledge of the chemistry of the organic pharmaceuticals
4. Appreciate the importance of organic pharmaceuticals in preventing and curing the disease.
5. To highlight the nature of the organic compounds used in Pharmaceuticals as drugs
6. Critical understanding of key reactions used in synthesis of therapeutics.

3. Course materials: Text books

a. T.R.Morrison and R. Boyd - Organic chemistry,
b. Bentley and Driver-Text book of Pharmaceutical chemistry
c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

Reference books

a. Organic chemistry – J.M.Cram and D.J.Cram
b. Organic chemistry- Brown
c. Advanced organic chemistry- Jerry March, Wiley
d. Organic chemistry- Cram and Hammered, Pine Hendrickson

4. Lecture wise programme: Topics

1 Structures and Physical properties:

a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non-ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
b. Acids and bases, Lowry bronsted and Lewis theories
c. Isomerism

2 Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides and Cycloalkanes.

3 Free radicals chain reactions of alkane: Mechanism, relative reactivity and stability

4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.

5 Nuclophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

7 Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

8 Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

9 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substituion in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

10 Elecrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic

aromatic substitution in alkyl benzene, side chain halogination of alkyl benzene, resonance stabilization of benzyl radical.

11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.

14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.

15 Oxidation reduction reaction.

16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Course Outcomes:

1. Learn about the many functional groups of organic medicines, the properties of these compounds, and the techniques for synthesizing these compounds.
2. Recognize the identification of pharmaceutical organic chemicals and their role in medicine.
3. Acquire knowledge and skills on Organic functional group detection of medicine and drugs
4. Identify/confirm the unknown organic compounds.
5. Familiarize with the fundamentals of synthesis of organic chemicals that are vital to the pharmaceutical industry.
6. Application of different type of organic reactions

Course Content

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilde / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-napthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Antharaquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotolune
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by:

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory : 2 Hrs. /Week

1. **objectives:** Upon completion of the course student shall be able to:
   a. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
   b. know the analysis of the inorganic pharmaceuticals their applications; and
   c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

2. **Course Outcomes:**
   1. Understand the principles and procedures of analysis of drugs
   2. Explain need and basic principle and applications of different titrations.
   3. Have knowledge of the analysis of the inorganic pharmaceuticals
   4. Appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.
   5. To highlight the limit of the inorganic impurities in Pharmaceuticals
   6. Critical analysis of radiopharmaceutical as therapeutics.

3. **Course materials: Text books**
   a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
   b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol -I & Vol-II
   c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

Reference books

a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
c. Analytical chemistry principles by John H. Kennedy
d. I.P.1985 and 1996, Govt. of India, Ministry of health

4. Lecture wise programme: Topics

1 Errors
2 Volumetric analysis
3 Acid-base titrations
4 Redox titrations
5 Non aqueous titrations
6 Precipitation titrations
7 Complexometric titrations
8 Theory of indicators
9 Gravimetry
10 Limit tests
11 Medicinal gases
12 Acidifiers
13 Antacids

14 Cathartics
15 Electrolyte replenishers
16 Essential Trace elements
17 Antimicrobials
18 Pharmaceutical aids
19 Dental Products
20 Miscellaneous compounds
21 Radio Pharmaceuticals

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Learn about the many groups of inorganic medicines, the sources of impurities, and the techniques for identifying impurities in pharmaceuticals.
2. Recognize the analysis of pharmaceutical inorganic chemicals and their role in medicine.
3. Acquire knowledge and skills on volumetric analytical methodologies.
4. Identify/confirm the unknown inorganic anions and cations.
5. Familiarize with the fundamentals of synthesis of inorganic chemicals that are vital to the pharmaceutical industry.
6. Application of different type of titration

Course Content

1. Limit test (6 exercises)
    a. Limit test for chlorides
    b. Limit test for sulphates
    c. Limit test for iron
    d. Limit test for heavy metals
    e. Limit test for arsenic
    f. Modified limit tests for chlorides and sulphates
2. Assays (10 exercises)
    a. Ammonium chloride- Acid-base titration
    b. Ferrous sulphate- Cerimetry
    c. Copper sulpahte- Iodometry
    d. Calcilugluconate- Complexometry
    e. Hydrogen peroxide – Permanganometry
    f. Sodium benzoate – Nonaqueous titration
    g. Sodium chloride – Modified volhard's method
    h. Assay of KI – KIO_3 titration
    i. Gravimetric estimation of barium as barium sulphate
    j. Sodium antimony gluconate or antimony potassium tartarate
3. Estimation of mixture (Any two exercises)
    a. Sodium hydroxide and sodium carbonate
    b. Boric acid and Borax
    c. Oxalic acid and sodium oxalate
4. Test for identity (Any three exercises)
    d. Sodium bicarbonate
    e. Barium sulphate
    f. Ferrous sulphate
    g. Potassium chloride

5. Test for purity (Any two exercises)
    1. Swelling power in Bentonite
    2. Acid neutralising capacity in aluminium hydroxide gel
    3. Ammonium salts in potash alum
    4. Adsorption power heavy Kaolin
    5. Presence of Iodates in KI
6. Preparations (Any two exercises)
    a. Boric acids
    b. Potash alum
    c. Calcium lactate
    d. Magnesium suphate

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment1&2	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory: 3 Hrs. /Week

REMEDIAL MATHEMATICS:

1. **Scope and objectives:** This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.
2. Upon completion of the course the student shall be able to: –
   g. Know Trignometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
   h. solve the problems of different types by applying theory; and
   i. appreciate the important applications of mathematics in pharmacy.
3. Course materials: Text books
   a. Differential calculus by Shantinarayan
   b. Text book of Mathematics for second year pre-university by Prof. B. M. Sreenivas

Reference books

a. Integral calculus by Shanthinarayan
b. Engineering mathematics By B.S.Grewal
c. Trigonometry Part-I By S.L.Loney

4. Lecture wise programme:

Topics

1	Algebra: Determinants, Matrices
2	Trigonometry: Sides and angles of a triangle, solution of triangles
3	Analytical Geometry: Points, Straight line, circle, parabola
4	Differential calculus: Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
5	Integral Calculus: Definite integrals, integration by substitution and by parts, Properties of definite integrals.
6	Differential equations: Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
7	Laplace transform: Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

BIOLOGY:

1. Scope and objectives: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduces to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.
2. Course materials: Text books
   a. Text book of Biology by S.B.Gokhale
   b. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

a. A Text book of Biology by B.V.Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. Lecture wise programme:

Topic

PART – A

1. Introduction
2 General organization of plants and its inclusions
3 Plant tissues
4 Plant kingdom and its classification
5 Morphology of plants
6 Root, Stem, Leaf and Its modifications
7 Inflorescence and Pollination of flowers
8 Morphology of fruits and seeds
9 Plant physiology
10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

1 Study of Animal cell
2 Study animal tissues
3 Detailed study of frog
4 Study of Pisces, Raptiles, Aves
5 Genearal organization of mammals
6 Study of poisonous animals

1.6 BIOLOGY (PRACTICAL)

Course Content

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives of the Subject:** Upon completion of the subject student shall be able to –
    h. describe the etiology and pathogenesis of the selected disease states;
    i. name the signs and symptoms of the diseases; and
    j. mention the complications of the diseases.

2. **Course Outcomes:**
    1. Summarize the concepts of cell injury and adaptation.
    2. Comprehend the etiology and pathogenesis of diseases.
    3. Interpret the disease course and predict the complications of the disease.
    4. Corelate the pathological changes with clinical course and identify the therapeutic targets.
    5. Describe the factors influencing transplantation of organs.
    6. Communicate effectively the disease prevention measures to the society.

Text books (Theory)

a. Pathologic basis of disease by- Cotran, Kumar, Robbins
b. Text book of Pathology- Harsh Mohan
c. Text book of Pathology- Y.M. Bhinde

Reference books (Theory)

a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. **Detailed syllabus and lecture wise schedule: Chapter**
    1. **Basic principles of cell injury and Adaptation**
        a) Causes, Pathogenesis and morphology of cell injury
        b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

    2. **Inflammation**
        a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
        b) Repairs of wounds in the skin, factors influencing healing of wounds

    3. **Diseases of Immunity**
        a) Introduction to Tand B cells
        b) MHC proteins or transplantation antigens
        c) Immune tolerance -Hypersensitivity

Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs - Autoimmunity Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.

- Acquired immune deficiency syndrome (AIDS)
- Amylodosis

4. **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.

5. **Types of shock, mechanisms, stages and management**
6. **Biological effects of radiation**

7. **Environmental and nutritional diseases**
   i. Air pollution and smoking- SO2, NO, NO2, and CO
   ii. Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.

8. Pathophysiology of common diseases

a. Parkinsonism
b. Schizophrenia
c. Depression and mania
d. Hypertension,
e. Stroke (ischaemic and hemorrhage)
f. Angina, CCF, Atherosclerosis, Myocardial infarction
g. Diabetes Mellitus
h. Peptic ulcer and inflammatory bowel diseases
i. Cirrhosis and Alcoholic liver diseases
j. Acute and chronic renal failure
k. Asthma and chronic obstructive airway diseases

9. Infectious diseases:

Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis-infective hepatitis.

4.Assignments:

Title of the Experiment

1 Chemical Mediators of inflammation
2 Drug Hypersensitivity
3 Cigarette smoking & its ill effects
4 Biological Effects of Radiation
5 Etiology and hazards of obesity

6 Complications of diabetes
7 Diagnosis of cancer
8 Disorders of vitamins
9 Methods in Pathology-Laboratory values of clinical significance
10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory: 3 Hrs. /Week

1. Objectives of the Subject:

Upon completion of the subject student shall be able to –

a. know the anatomy, identification, growth factors and sterilization of microorganisms;
b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
c. do estimation of RNA and DNA and there by identifying the source;
d. do cultivation and identification of the microorganisms in the laboratory;
e. do identification of diseases by performing the diagnostic tests; and
f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

2. Course Outcomes:

1. Illustrate the basic knowledge of microbiology with pharmaceutical sciences.
2. Apply techniques for identification and isolation of microorganisms.
3. Understand process of sterilization and disinfection
4. Conceptualize the significance of immunological reactions.
5. Implement of diagnostic testing methods for infectious disease
6. Justify the use of microorganisms considering the ecological and ethical issues.

Text books (Theory)

a. Vanitha Kale and Kishor Bhusari ― Applied Microbiology ‖ Himalaya Publishing house Mumbai.
b. Mary Louis Turgeon ― Immunology and Serology in Laboratory Medicines‖ 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
c. Harsh Mohan, ― Text book of Pathology‖ 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

a. Prescot L.M., Jarley G.P Klein D.A ―Microbiology‖ 2nd- edition Mc Graw Hill Company Inc
b. Rawlins E.A.‖Bentley's Text Book of Pharmaceutics‖ B ailliere Tindals 24-28 London 1988
c. Forbisher ― Fundamentals of Microbiology‖ Philidelphia W.B. Saunders.
d. Prescott L.M. Jarley G.P., Klein.D.A. ― Microbiology.‖2nd edition WMC Brown Publishers, Oxford. 1993
e. War Roitt, Jonathan Brostoff, David male, ― Immunology‖3rd edition 1996, Mosby-year book Europe Ltd, London.
f. Pharmacopoeia of India, Govt of India, 1996.

3. **Detailed syllabus and lecture wise schedule :** Title of the topic

1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.

2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.

3 Nutritional requirements, growth and cultivation of bacteria and virus.
Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.

4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.

5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations.

Brief information on Validation.

6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic,, virucidal activities, evaluation of preservatives in pharmaceutical preparations.

7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity (active and passive) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.

8 Diagnostic tests: Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite.

9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B2 and B12. Standardisation of vaccines and sera.

10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Course Outcomes:

1. Implement good laboratory practices in pharmaceutical microbiology.
2. Prepare, isolate, and identify the culture media for various microorganisms.
3. Assess aseptic conditions in pharmaceutical laboratories as per GLP
4. Apply sterilization and disinfection techniques in pharmacy.
5. Determine the microbial count using modern analytical tools
6. Compute, analyze and record data.

Title of the Experiment:

1. Study of apparatus used in experimental microbiology*.
2. Sterilisation of glass ware's. Preparation of media and sterilisation.*
3. Staining techniques – Simple staining ; Gram's staining ; Negative staining**
4. Study of motility characters*.
5. Enumeration of micro-organisms (Total and Viable)*
6. Study of the methods of isolation of pure culture.*
7. Bio chemical testing for the identification of micro*-organisms.
8. Cultural sensitivity testing for some micro-organisms.*
9. Sterility testing for powders and liquids.*
10. Determination of minimum inhibitory concentration.*
11. Microbiological assay of antibiotics by cup plate method.*
12. Microbiological assay of vitamins by Turbidometric method**
13. Determination of RWC.**
14. Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

1. Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories (other sterization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
   a. Report of recent microbial techniques developed in diagnosing some common diseases.
   b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.

5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives: Upon completion of the course student shall be able to:**
    a. understand the basic principles of cultivation, collection and storage of crude drugs;
    b. know the source, active constituents and uses of crude drugs; and
    c. appreciate the applications of primary and secondary metabolites of the plant.

2. Course Outcomes:

1. Understand the concept and scope of Pharmacognosy with various systems.
2. Explain the concept of classification of crude drugs including primary and secondary metabolites and natural fibers.
3. Comprehend the concepts of cultivation and collection of crude drugs for organized and unorganized drugs.
4. Discover the concepts of processing production, storage, and adulteration of crude drugs.
5. Describe the various extraction and evaluation techniques for the herbal drugs along with uses and chemical nature.
6. Carry out the microscopic and morphological evaluation of crude drugs with respect to cellular contents.

3. Course materials:

Text books

a. Pharmacognosy by G.E. Trease & W.C.Evans.
b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

Reference books

a. Pharmacognosy by Brady &Tyler.E.
b. Pharmacognosy by T.E.Wallis.
c. Pharmacognosy by C.S. Shah & Qadery.
d. Pharmacognosy by M.A. Iyengar**.**

4. Lecture wise programme: Topics

1. Introduction.
2. Definition, history and scope of Pharmacognosy.
3. Classification of crude drugs.
4. Cultivation, collection, processing and storage of crude drugs.
5. Detailed method of cultivation of crude drugs.
6. Study of cell wall constituents and cell inclusions.
7. Microscopical and powder Microscopical study of crude drugs.
8. Study of natural pesticides.
9. Detailed study of various cell constituents.
10. Carbohydrates and related products.

11. Detailed study carbohydrates containing drugs.(11 drugs)
12. Definition sources, method extraction, chemistry and method of analysis of lipids.
13. Detailed study of oils.
14. Definition, classification, chemistry and method of analysis of protein.
15. Study of plants fibers used in surgical dressings and related products.
16. Different methods of adulteration of crude drugs.

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical : 3 Hrs./Week

Course Outcomes:

1. Evaluate crude drugs based on chemical tests
2. Identify the various leaves on the basis of quantitative microscopy (with camera lucida) like stomatal index, palisade ratio etc.
3. Explain the crude drugs based on microscopical characters
4. Explore different types of methods for standardization of crude drugs, i.e. ash value, foaming index, extractive values etc. along with morphology.
5. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
6. Study of various types values as iodine value, saponification value, ester value, acid value.

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

1. Introduction of Pharmacognosy laboratory and experiments.
2. Study of cell wall constituents and cell inclusions.
3. Macro, powder and microscopic study of Datura.
4. Macro, powder and microscopic study of Senna.
5. Macro, powder and microscopic study of Cassia.cinnamon.
6. Macro, powder and microscopic study of Cinchona.
7. Macro, powder and microscopic study of Ephedra.
8. Macro, powder and microscopic study of Quassia.
9. Macro, powder and microscopic study of Clove
10. Macro, powder and microscopic study of Fennel.
11. Macro, powder and microscopic study of Coriander.
12. Macro, powder and microscopic study of Isapgol.
13. Macro, powder and microscopic study of Nux vomica.
14. Macro, powder and microscopic study of Rauwolfia.
15. Macro, powder and microscopic study of Liquorice.
16. Macro, powder and microscopic study of Ginger.
17. Macro, powder and microscopic study of Podophyllum.
18. Determination of Iodine value.
19. Determination of Saponification value and unsaponifiable matter.
20. Determination of ester value.
21. Determination of Acid value.
22. Chemical tests for Acacia.
23. Chemical tests for Tragacanth.
24. Chemical tests for Agar.

25. Chemical tests for Starch.
26. Chemical tests for Lipids. (castor oil,sesame oil, shark liver oil,bees wax)
27. Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

2.4 PHARMACOLOGY – I (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
   a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
   b. handle and carry out the animal experiments;
   c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
   d. correlate and apply the knowledge therapeutically.

2. Course Outcomes:

1. Describe the fundamental concepts of pharmacology.
2. Relate the molecular basis of drug action with clinical uses.
3. Comprehend the adverse effects and drug interactions.
4. Justify correlation of pharmacology with other bio medical sciences.
5. Apply the pharmacological knowledge in the prevention and treatment of various diseases.
6. Recommend measures to minimize adverse drug effects and drug interactions to the society.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The Pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
c. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical):

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. **Detailed syllabus and lecture wise schedule:** Title of the topic

1. General Pharmacology

a) Introduction, definitions and scope of pharmacology
b) Routes of administration of drugs
c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
d) Pharmacodynamics
e) Factors modifying drug effects
f) Drug toxicity - Acute, sub- acute and chronic toxicity.
g) Pre-clinical evaluations
h) Drug interactions

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. Pharmacology of drugs acting on ANS

a) Adrenergic and antiadrenergic drugs
b) Cholinergic and anticholinergic drugs
c) Neuromuscular blockers
d) Mydriactics and miotics
e) Drugs used in myasthenia gravis
f) Drugs used in Parkinsonism

3. Pharmacology of drugs acting on cardiovascular system

a) Antihypertensives
b) Anti-anginal drugs
c) Anti-arrhythmic drugs
d) Drugs used for therapy of Congestive Heart Failure
e) Drugs used for hyperlipidaemias

4. Pharmacology of drugs acting on Central Nervous System

a) General anesthetics
b) Sedatives and hypnotics
c) Anticonvulsants

d) Analgesic and anti-inflammatory agents
e) Psychotropic drugs
f) Alcohol and methyl alcohol
g) CNS stimulants and cognition enhancers
h) Pharmacology of local anaesthetics

5. Pharmacology of Drugs acting on Respiratory tract

a) Bronchodilators
b) Mucolytics
c) Expectorants
d) Antitussives
e) Nasal Decongestants

6. Pharmacology of Hormones and Hormone antagonists

a. Thyroid and Antithyroid drugs
b. Insulin, Insulin analogues and oral hypoglycemic agents
c. Sex hormones and oral contraceptives
d. Oxytocin and other stimulants and relaxants

7. Pharmacology of autocoids and their antagonists

a. Histamines and Antihistaminics
b. 5-Hydroxytryptamine and its antagonists
c. Lipid derived autocoids and platelet activating factor

2.5 COMMUNITY PHARMACY (THEORY)

Theory: 2 Hrs. /Week

1. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know pharmaceutical care services;
   b. know the business and professional practice management skills in community pharmacies;
   c. do patient counselling & provide health screening services to public in community pharmacy;
   d. respond to minor ailments and provide appropriate medication;
   e. show empathy and sympathy to patients; and
   f. appreciate the concept of Rational drug therapy.

2. Course Outcomes:

1. Understand the role, responsibility establishment procedure and management of community pharmacy
2. Handle and interpret prescriptions to avoid drug-drug and drug-food interaction
3. Implement inventory control and drug management system in community pharmacy
4. Apply ethical practices for rational drug therapy, essential drug and patient counseling
5. Counsel the patients and provide health screening services in the management of minor and chronic diseases
6. Promote the role of community pharmacist in the society to develop professional image

Text Books:

a. Health Education and Community Pharmacy by N.S.Parmar.
b. WHO consultative group report.
c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

a. Handbook of pharmacy – health care.Edt. Robin J Harman. The Pharmaceutical press.
b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

1. Synopsis 10
2. Major Experiment 30

(Counselling of patients with specific diseases – emphasis should be given on

Counselling introduction, content, process and conclusion)

3. Minor Experiment(Ability to measure B.P/ CBG / Lung function) 15
4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management 15
5. Viva – Voce 10

4. Lecture wise programme:

Topics

1. **Definition, scope, of community pharmacy Roles and responsibilities of Community pharmacist**
2. **Community Pharmacy Management**
   a) Selection of site, Space layout, and design
   b) Staff, Materials- coding, stocking
   c) Legal requirements
   d) Maintenance of various registers
   e) Use of Computers: Business and health care soft wares
3. **Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.
4. **Inventory control in community pharmacy**
   Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock
5. **Pharmaceutical care**
   Definition and Principles of Pharmaceutical care.
6. **Patient counselling**
   Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design, & layouts, advisory labels
7. **Patient medication adherence**
   Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
8. **Health screening services**
   Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function and Cholesterol testing
9. **OTC Medication- Definition, OTC medication list & Counselling**
10. **Health Education**
    WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
    Commonly occurring Communicable Diseases, causative agents,
    Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy,
    Syphilis, Gonorrhea and AIDS
    Balance diet, and treatment & prevention of deficiency disorders
    Family planning – role of pharmacist

11. **Responding to symptoms of minor ailments**
    Relevant pathophysiology, common drug therapy to, Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.
12. **Essential Drugs concept and Rational Drug Therapy Role of community pharmacist**
13. **Code of ethics for community pharmacists**

2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualised therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. discuss the controversies in drug therapy;
   i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

2. **Course Outcomes:**
   1. Describe the etiopathogenesis of diseases and the rationale of drug therapy.
   2. Relate the patient specific parameters before initiating drug therapy.
   3. Illustrate the drug therapy controversies.
   4. Sketch individualized therapeutic plan based on diagnosis of patient.
   5. Devise the pharmacotherapeutic care plan in various disease conditions.
   6. Summarize the therapeutic approach to the management of diseases and their monitoring parameters.

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.

b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
d. Applied Therapeutics:The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

f. Relevant review articles from recent medical and pharmaceutical literature.

3. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

1. **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias
2. **Respiratory system:** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
   Endocrine system: Diabetes mellitus – newer trends in antihyperglycemic therapies and insulin therapies Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
3. **General prescribing guidelines for**
   a. Paediatric patients
   b. Geriatric patients
   c. Pregnancy and breast feeding
4. **Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial**
5. **Introduction to rational drug use**

Definition, Role of pharmacist Essential drug concept Rational drug formulations

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. List the subjective-objective parameters.
2. Review the clinical presentation and diagnosis of disease state.
3. Apply the pharmacotherapeutic principles in disease management.
4. Prepare pharmaceutical care plan.
5. Revise the pharmaceutical care plan as per pharmacotherapy problems.
6. Recommend the monitoring parameters and outcome measures.

Practicals:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives of the Subject Upon completion of the subject student shall be able to:**
   a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
   b. carry out the animal experiments confidently,
   c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
   d. correlate and apply the knowledge therapeutically.

2.Course Outcomes:

1. Relate the molecular basis of drug action with clinical uses.
2. Comprehend the adverse effects and drug interactions.
3. Understand gene therapy and targeting.
4. Justify correlation of pharmacology with other biomedical sciences.
5. Apply the pharmacological knowledge in the prevention and treatment of various diseases.
6. Recommend measures to minimize adverse drug effects and drug interactions to the society.

Text books (Theory)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The Pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical) :

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3.Detailed syllabus and lecture wise schedule: Title of the topic

1. Pharmacology of Drugs acting on Blood and blood forming agents

a) Anticoagulants
b) Thrombolytics and antiplatelet agents
c) Haemopoietics and plasma expanders

2. Pharmacology of drugs acting on Renal System

a) Diuretics
b) Antidiuretics

3. Chemotherapy

a) Introduction
b) Sulfonamides and co-trimoxazole
c) Penicillins and Cephalosporins
d) Tetracyclins and Chloramphenicol
e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
f) Quinolines and Fluroquinolines
g) Antifungal antibiotics
h) Antiviral agents
i) Chemotherapy of tuberculosis and leprosy
j) Chemotherapy of Malaria
k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
l) Pharmacology of Anthelmintic drugs
m) Chemotherapy of cancer (Neoplasms)

4. Immunopharmacology

Pharmacology of immunosuppressants and stimulants

5. Principles of Animal Toxicology Acute, sub-acute and chronic toxicity

6. The dynamic cell: The structures and functions of the components of the cell

a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
c) DNA replication: General, bacterial and eukaryotic DNA replication.

d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

The Gene: Genome structure and function:

a) Gene structure: Organization and elucidation of genetic code.
b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities.
Oncogenes and tumor suppressor genes.
The gene sequencing, mapping and cloning of human disease genes.
Introduction to gene therapy and targeting.
Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

1. Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
2. Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
3. Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
4. Genes VIII by Lewin, B., (2004)
5. Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
6. Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
7. Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.1 PHARMACOLOGY – II (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Understand the importance of use of animals in drug discovery and development.
2. Apply ethical principles in animal experimentation.
3. Demonstrate the use of common experimental pharmacology instruments.
4. Outline the principles and applications of bioassay
5. Evaluate the effect of drugs using various techniques in experimental pharmacology.
6. Appreciate correlation of pharmacology with related medical sciences.

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three-point method.
8. To record the dose response curve of Histamine using isolated guinea -pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea -pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three-point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
    a) Analgesic property of drug using analgesiometer.
    b) Antiinflammatory effect of drugs using rat-paw edema method.
    c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
    d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
    e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
    f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	**20**	**70**
Duration	**3hrs**	**4hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes:

1. Understand the concept of QA, SQC, TQM and ICH guidelines
2. Integrate physicochemical and electrochemical properties of drugs with analytical methods
3. Comprehend the importance of instrumentation of various analytical techniques
4. Remember the principle, advantages, challenges, and applications of electrochemical analysis
5. Remember the principle, advantages, challenges, and applications of spectroscopic analysis
6. Study of X Ray/ Thermal methods of analysis

Course Content

1. Quality Assurance:

a. Introduction, sources of quality variation, control of quality variation.
b. Concept of statistical quality control.
c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
d. GLP, ISO 9000.
e. Total quality management, quality review and documentation.
f. ICH- international conference for harmonization-guidelines.
g. Regulatory control.

2. Chromatography:

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

a. **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
b. **TLC:** Introduction, principle, techniques, Rf value and applications.
c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
d. Ion-exchange chromatography: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
e. **HPLC:** Introduction, theory, instrumentation, and applications.
f. **HPTLC:** Introduction, theory, instrumentation, and applications.
g. **Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors-Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.

h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
i. **Gel filtration and affinity chromatography:** Introduction, technique, applications.

3. Electrometric Methods:

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

a. **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
b. **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
c. **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. Spectroscopy:

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. Absorption Spectroscopy:

-Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following Detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

-Infrared Spectroscopy: Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectro-meter – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors– Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

-Fluorimetric Analysis: Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

b. Flame Photometry: Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.

c. Atomic Absorption Spectrometry: Introduction, Theory, types of electrodes, instrumentation and applications.

d. Atomic Emission Spectroscopy: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

e. NMR & ESR (introduction only): Introduction, theoretical aspects and applications.

f. Mass Spectroscopy: (Introduction only) – Fragmentation, types of ions produced mass spectrum and applications.

g.Polarimetry: (Introduction only) – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.

h.X-RAY Diffraction: (Introduction only) – Theory, reciprocal lattice concept, diffraction patterns and applications.

i. Thermal Analysis: Introduction, instrumentation, applications, and DSC and DTA.

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Understand the significance of analysis in analytical chemistry by UV spectroscopy
2. Estimation of drugs using Fluorimetric methods for drug analysis
3. Analyze the drugs using colourimetry, Nepheloturbidimetry and Flame photometry
4. Demonstrate analytical skills for evaluation of drugs by HPLC, GC and DSC
5. Observe, record, and communicate experimental data
6. To develop the interpretation skills

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of a acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.

7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory: 3 Hrs. /Week

1. Objectives of the Subject Upon completion of the subject student shall be able to –

a. know the pathophysiology of selected disease states and the rationale for drug therapy
b. know the therapeutic approach to management of these diseases;
c. know the controversies in drug therapy;
d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

2. Course Outcomes:

1. Describe the etiopathogenesis of diseases and the rationale of drug therapy.
2. Relate the patient specific parameters before initiating drug therapy.
3. Illustrate the drug therapy controversies.
4. Sketch individualized therapeutic plan based on diagnosis of patient.
5. Devise the pharmacotherapeutic care plan in various disease conditions.
6. Summarize the therapeutic approach to the management of diseases and their monitoring parameters.

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –Title of the topic

1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis
2. **Musculoskeletal disorders**
   Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
3. **Renal system** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, recent advances in management and Chemotherapy of breast cancer, leukemia. Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis

5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Course Outcomes:

1. List the subjective-objective parameters.
2. Review the clinical presentation and diagnosis of disease state.
3. Apply the pharmacotherapeutic principles in disease management.
4. Prepare pharmaceutical care plan.
5. Revise the pharmaceutical care plan as per pharmacotherapy problems.
6. Recommend the monitoring parameters and outcome measures.

Practicals:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory: 2 Hrs. /Week

1. **Objectives of the Subject: Upon completion of the subject student shall be able to (Know, do, and appreciate) –**
   a. practice the Professional ethics;
   b. understand the various concepts of the pharmaceutical legislation in India;
   c. know the various parameters in the Drug and Cosmetic Act and rules;
   d. know the Drug policy, DPCO, Patent and design act;
   e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
   f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
   g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

2. Course Outcomes:

1. Apply practice the Professional ethics; Comprehend various Indian Pharmaceutical Acts and Laws
2. Understand the various concepts of the pharmaceutical legislation in India and their implications in the development and marketing of pharmaceuticals
3. Know the various parameters in the Drug and Cosmetic Act and rules and Prioritize other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.
4. Remember the Drug policy, DPCO, Patent and design act
5. Understand the labeling requirements and packaging guidelines for drugs and cosmetics;
6. Be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act

Text books (Theory)

Mithal, B M. Textbook of Forensic Pharmacy. Calcutta: National; 1988.

Reference books (Theory)

a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
c. Reports of the Pharmaceutical Enquiry Committee
d. I.D.M.A., Mumbai. DPCO 1995
e. Various reports of Amendments.
f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
g. Eastern Book Company. The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3.Detailed syllabus and lecture wise schedule: Title of the topic

1. **Pharmaceutical Legislations** – A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.**

   Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.

   Sales, Import, labeling and packaging of Drugs and Cosmetics Provisions Relating to Indigenous Systems.

   Constitution and Functions of DTAB,DCC,CDL. Qualification and duties –Govt. analyst and Drugs Inspector.
4. **Pharmacy Act –1948.**

   Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**

   Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price Control Order & National Drug Policy (Current).**
10. **Prevention of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes:

1. To understand the chemistry of drugs with respect to their biological activity
2. To know the metabolism, adverse effect, and therapeutic activity of drugs.
3. To understand the different modern techniques of drug design & describe the mechanism actions of categories of drugs
4. To relate influence of substituents on the physico-chemical properties and biological activity of drugs SAR of all classes of drugs.
5. Explain the therapeutic uses and adverse reactions of drugs belonging to different classes for the benefit of society
6. Write the routes of synthesis of drugs & sketch the Structures.

Course Content

1. **Modern concept of rational drug design:** A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.
   A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.
2. **Anti-infective agents**
   a) Local anti-infective agents
   b) Preservatives
   c) Antifungal agents
   d) Urinary tract anti-infectives
   e) Antitubercular agents
   f) Antiviral agents and Anti AIDS agents
   g) Antiprotozoal agents
   h) Anthelmentics
   i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
   a) Antihypertensive agents
   b) Antianginal agents and vasodilators
   c) Antiarrhythmic agents
   d) Antihyperlipidemic agents
   e) Coagulants and Anticoagulants
   f) Endocrine
8. Hypoglycemic agents

9. Thyroid and Antithyroid agents
10. Diureties
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. To understand Nomenclature of simple organic compounds in different classes, make 3D S tereomodels & to apply principles of organic chemistry for synthesis of drugs with emphasis on environment and safety
2. Determination of some important physical properties like melting point, boiling point, solubility, & to learn demonstrate TLC techniques for monitoring reactions and checking purity of synthesized compounds.
3. Use principles of Purification of Organic compounds & qualitative analysis for identification and structural confirmation of synthesized compounds.
4. Able to understand the Synthesis of organic compounds and study about principles, named reactions and mechanisms involved.
5. Compute, analyze and record the observations
6. Evaluate the need of advancements in the therapy of diseases

Course Content

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refra ctivity of compounds for QSAR analysis.

Reference Books:

1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
2. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
3. Burgers, Medicinal Chemistry, M.E.,Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
4. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
5. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
6. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
7. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
8. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
9. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory: 2 Hrs. /Week

1. **Objectives:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
   1. understand the principle involved in formulation of various pharmaceutical dosage forms;
   2. prepare various pharmaceutical formulation;
   3. perform evaluation of pharmaceutical dosage forms; and
   4. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

2. **Course Outcomes:**
   1. Understand the principle involved in formulation of various pharmaceutical dosage forms.
   2. Prepare various pharmaceutical formulation.
   3. Justify the composition, containers, labels, expiry period, economy, acceptance drug Products.
   4. Perform evaluation of pharmaceutical dosage forms.
   5. Understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.
   6. Adapt Good Laboratory Practices.

Text books (Theory)

a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
b. Rowlings Text book of Pharmaceutics
c. Tutorial Pharmacy – Cooper &Gun

Reference books (Theory)

a. Remington's Pharmaceutical Sciences
b. USP/BP/IP

3. Detailed syllabus and lecture wise schedule: Title of the topic

1. **Pharmaceutical dosage form- concept and classification**
2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. Parenterals Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization

6. Ophthalmic preparations (Semi – Solids): Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
7. Definition and concept of Controlled and novel Drug delivery systems with available examples, viz. parentral, trans dermal, buccal, rectal, nasal, implants, ocular

3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Review of marketed drug products of various dosage forms.
2. Justify the composition, containers, labels, expiry period, economy, acceptance drug Products.
3. Formulate solid, liquid, semisolid, parenteral pharmaceuticals and cosmetics.
4. Select appropriate manufacturing equipment's.
5. Evaluate quality of pharmaceuticals and cosmetics.
6. Adapt Good Laboratory Practices.

List of Experiments:

1. **Manufacture of Tablets**
   a. Ordinary compressed tablet-wet granulation
   b. Tablets prepared by direct compression.
   c. Soluble tablet.
   d. Chewable tablet.
2. **Formulation and filling of hard gelatin capsules**
3. **Manufacture of parenterals**
   a. Ascorbic acid injection
   b. Calcium gluconate injection
   c. Sodium chloride infusion.
   d. Dextrose and Sodium chloride injection/ infusion.

4 Evaluation of Pharmaceutical formulations (QC tests)

   a. Tablets
   b. Capsules
   c. Injections

5. **Formulation of two liquid oral preparations and evaluation by assay**
   a. Solution: Paracetamol Syrup
   b. Antacid suspensions- Aluminum hydroxide gel
6. **Formulation of semisolids and evaluation by assay**
   a. Salicyclic acid and benzoic acid ointment
   b. Gel formulation Diclofenac gel
7. **Cosmetic preparations**
   a. Lipsticks
   b. Cold cream and vanishing cream
   c. Clear liquid shampoo
   d. Tooth paste and tooth powders.

8. **Tablet coating (demonstration)**

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives:** At completion of this subject it is expected that students will be able to understand –

    a. the pathophysiology of selected disease states and the rationale for drug therapy;
    b. the therapeutic approach to management of these diseases;
    c. the controversies in drug therapy;
    d. the importance of preparation of individualised therapeutic plans based on diagnosis;
    e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
    f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
    g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
    h. to discuss the controversies in drug therapy;
    i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
    j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

2. Course Outcomes:

1. Describe the pathophysiology of diseases and the rationale for drug therapy.
2. Illustrate the therapeutic approach to management of the diseases.
3. Demonstrate the controversies in drug therapy.
4. Sketch the individualized therapeutic plan based on diagnosis of patient.
5. Design patient's specific parameters relevant in initiating drug therapy and monitoring drug therapy.
6. Summarize the therapeutic approach to management of the diseases with reference to latest available evidences.

Course Content

1. **Gastrointestinal system:** Peptic ulcer disease, Gastro-Oesophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, recent advances in management of Viral hepatitis, Jaundice, and Drug induced liver disorders.
2. **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
3. **Nervous system:** Epilepsy – ILAE and AES recommendations in refractory epilepsy, Parkinson's disease – Clinical features and evidence-based management, Stroke - AHA/ASA's guidance on IS and ICH management, Recent development in the management of Alzheimer's disease
4. **Psychiatry disorders:** Schizophrenia, affective disorders, anxiety disorders, sleep disorders, obsessive-compulsive disorders
5. Pain management including Pain pathways, neuralgias, headaches.
6. New approaches in Evidence Based Medicine

Text Books

b. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
c. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

1. Pathologic basis of disease - Robins SL, W.B.Saunders publication
2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
3. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda – Kimble MA
4. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
5. Relevant review articles from recent medical and pharmaceutical literature.

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. List the subjective-objective parameters.
2. Review the clinical presentation and diagnosis of disease state.
3. Apply the pharmacotherapeutic principles in disease management.
4. Prepare pharmaceutical care plan.
5. Revise the pharmaceutical care plan as per pharmacotherapy problems.
6. Recommend the monitoring parameters and outcome measures.

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Course Content

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

1. **Gastrointestinal system:** Peptic ulcer disease, Gastro-Oesophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, recent advances in management of Viral hepatitis, Jaundice, and Drug induced liver disorders.
2. **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
3. **Nervous system:** Epilepsy – ILAE and AES recommendations in refractory epilepsy, Parkinson's disease – Clinical features and evidence-based management, Stroke - AHA/ASA's guidance on IS and ICH management, Recent development in the management of Alzheimer's disease
4. **Psychiatry disorders:** Schizophrenia, affective disorders, anxiety disorders, sleep disorders, obsessive-compulsive disorders
5. Pain management including Pain pathways, neuralgias, headaches.
6. New approaches in Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.

3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2 HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

1. **Objectives:** Upon completion of the course, the student shall be able to –
    a. know various drug distribution methods;
    b. know the professional practice management skills in hospital pharmacies;
    c. provide unbiased drug information to the doctors;
    d. know the manufacturing practices of various formulations in hospital set up;
    e. appreciate the practice based research methods; and
    f. appreciate the stores management and inventory control.

2. **Course Outcomes:**
    1. Describe the stores management and inventory control.
    2. Recognize and explain roles and responsibilities of hospital pharmacist.
    3. Prepare and practice therapeutic guidelines and hospital formulary.
    4. Illustrate and employ various drug distribution methods in hospital.
    5. Design and develop central sterile supply services.
    6. Describe distribution of Narcotic and other controlled substances.

Text books: (latest editions)

a. Hospital pharmacy by William.E. Hassan
b. A text book of Hospital Pharmacyby S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

a. WHO consultative group report.
b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. **Lecture wise programme**:

Topics

1. 1Hospital - its Organisation and functions
2. Hospital pharmacy-Organisation and management
    a) Organizational structure-Staff, Infrastructure & work load statistics
    b) Management of materials and finance
    c) Roles & responsibilities of hospital pharmacist
3. The Budget – Preparation and implementation
4. Hospital drug policy
    a) Pharmacy and Therapeutic committee (PTC)
    b) Hospital formulary
    c) Hospital committees -Infection committee-Research and ethical committee
    d) developing therapeutic guidelines

e) Hospital pharmacy communication - Newsletter

5. Hospital pharmacy services
   a) Procurement & warehousing of drugs and Pharmaceuticals
   b) Inventory control Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock
   c) Drug distribution in the hospital
      i. Individual prescription method
      ii. Floor stock method
      iii. Unit dose drug distribution method
   d) Distribution of Narcotic and other controlled substances
   e) Central sterile supply services – Role of pharmacist

6. Manufacture of Pharmaceutical preparations
   a) Sterile formulations – large and small volume parenterals
   b) Manufacture of Ointments, Liquids, and creams
   c) Manufacturing of Tablets, granules, capsules, and powders
   d) Total parenteral nutrition

7. Continuing professional development programs Education and training
8. Radio Pharmaceuticals – Handling and packaging
9. Professional Relations and practices of hospital pharmacist

4.2 HOSPITAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Describe inventory control.
2. Review and summarise unbiased drug information.
3. Solve drug information queries using various tools.
4. Categorise various drug interactions.
5. Design and develop hospital formulary.
6. Evaluate the prescription for various drug interactions.

Course Content

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3 CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

1. Objectives:

Upon completion of the subject student shall be able to (Know, do, appreciate) –

a. monitor drug therapy of patient through medication chart review and clinical review;
b. obtain medication history interview and counsel the patients;
c. identify and resolve drug related problems;
d. detect, assess and monitor adverse drug reaction;
e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
f. retrieve, analyse, interpret and formulate drug or medicine information.

2. Course Outcomes:

1. Identify drug related problems in patient therapy through monitoring of drug therapy, medication chart review and clinical review.
2. Interpret laboratory results (as monitoring parameters in therapeutics) of diseases.
3. Prepare relevant drug or medicine information and counsel the patients.
4. Solve and manage Adverse Drug Reactions.
5. Formulate evidence-based drug information for better practices to be followed by physicians.
6. Justify and appraise quality assurance of clinical pharmacy services.

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

3. **Detailed syllabus and lecture wise schedule: Title of the topic**

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
   a) Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
   b) Ward round participation
   c) Adverse drug reaction management
   d) Drug information and poisons information
   e) Medication history
   f) Patient counseling
   g) Drug utilisation evaluation (DUE) and review (DUR)
   h) Quality assurance of clinical pharmacy services

3. **Patient data analysis**

   The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.

4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
   a. Haematological, Liver function, Renal function, thyroid function tests
   b. Tests associated with cardiac disorders
   c. Fluid and electrolyte balance
   d. Microbiological culture sensitivity tests
   e. Pulmonary Function Tests
5. **Drug & Poison information**
   a. Introduction to drug information resources available
   b. Systematic approach in answering DI queries
   c. Critical evaluation of drug information sources using drug and clinical database.
   d. Preparation of written and verbal reports
   e. Establishing a Drug Information Centre
   f. Poisons information- organization & information resources
6. **Pharmacovigilance**
   a. Scope, definition and aims of pharmacovigilance
   b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
   c. Reporting, evaluation, monitoring, preventing & management of ADRs
   d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts including medication reconciliation and medication therapy management.
9. Critical evaluation of biomedical literature
10. Medication errors - strategies to prevent medication errors.

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Identify clinically significant data from the medical case files.
2. Relate the clinically significant data with patients medical condition.
3. Compare the patient's subjective and objective data to interpret diagnosis.
4. Practice drug and poison information services.
5. Assess adverse drug reactions, and medication errors.
6. Recommend suitable drug therapy changes for best possible patient outcomes.

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

a. Answering drug information questions (4 Nos)
b. Patient medication counselling (4 Nos)
c. Case studies related to laboratory investigations (4 Nos)
d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

Course Outcomes:

1. Define the clinical study design.
2. Describe suitable research methodology.
3. Compute sample size for research study.
4. Categorise the data for variable correlation.
5. Analyse the data for statistical means.
6. Conclude the study results.

1. Detailed syllabus and lecture wise schedule

1. Research Methodology

a) Types of clinical study designs: Case studies, observational studies, interventional studies,
b) Designing the methodology
c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
d) Report writing and presentation of data

2. Biostatistics

2.1 a) Introduction
b) Types of data distribution
c) Measures describing the central tendency distributions- average, median, mode
d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 Data graphics

Construction and labelling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots

2.3 Basics of testing hypothesis

a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
b) Level of significance (Parametric data)- student's test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one-way ANOVA)
d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.
e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system

Drug Information Retrieval & Storage:

Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval

Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes:

1. Understand the concept of absorption, distribution, metabolism and excretion of drug.
2. Calculate pharmacokinetic parameters of drugs.
3. Implement effective compartmental modelling in pharmacokinetic studies
4. Define multiple dosage regimen for effective therapeutic action
5. Design bioavailability-bioequivalence study protocol to establish the quality of generic drugs.
6. Explore application of linear and non-linear pharmacokinetic principles

Course Content

1. **Biopharmaceutics**
    1. Introduction to Biopharmaceutics
        a. Absorption of drugs from gastrointestinal tract.
        b. Drug Distribution.
        c. Drug Elimination.
2. **Pharmacokinetics**
    2. Introduction to Pharmacokinetics.
        a. Mathematical model
        b. Drug levels in blood.
        c. Pharmacokinetic model
        d. Compartment models
        e. Pharmacokinetic study.
    3. One compartment open model.
        a. Intravenous Injection (Bolus)
        b. Intravenous infusion.
    4. Multiompartment models.
        a. Two compartment open model.
        b. IV bolus, IV infusion and oral administration
    5. Multiple – Dosage Regimens.
        a. Repititive Intravenous injections – One Compartment Open Model
        b. Repititive Extravascular dosing – One Compartment Open model
        c. Multiple Dose Regimen – Two Compartment Open Model
    6. Nonlinear Pharmacokinetics.
        a. Introduction
        b. Factors causing Non-linearity.
        c. Michaelis-menton method of estimating parameters.
    7. Noncompartmental Pharmacokinetics.
        a. Statistical Moment Theory.
        b. MRT for various compartment models.
        c. Physiological Pharmacokinetic model.

8. Bioavailability and Bioequivalence.

a. Introduction.
b. Bioavailability study protocol.
c. Methods of Assessment of Bioavailability
d. Virtual Bioequivalence
e. introduction to SimCyp simulator
f. regulatory aspects of Virtual bioequivalence

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical: 3 Hrs./Week

Course Outcomes:

1. Improve dissolution and solubility characteristics of slightly soluble drugs
2. Understand the effect of time and concentration of drug on plasma-protein binding
3. Determine elimination half-life, pharmacokinetic parameters using given urinary excretion data
4. Execute absorption studies in animal intestine
5. Design bioavailability-bioequivalence study protocol to establish the quality of generic drugs.
6. Compute, analyze various pharmacokinetic parameters using blood plasma data

Course Content

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of Ka, Ke, t1/2, Cmax, AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed. (eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on Content time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
c. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
f. Biopharmaceutics; By Swarbrick
g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

Course Outcomes:

1. Describe general principles involved in the management of poisoning.
2. Identify and locate clinical symptoms of acute poisoning.
3. Relate the type of poisoning and practice various antidotes.
4. Categorise the venomous snake bites and type of toxins based upon clinical symptoms.
5. Explain treatment of substance abuse and dependence.
6. Evaluate and explain toxicokinetics.

Course Content

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination – gastric lavage and irrigation.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
   a. Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
   b. Opiates overdose.
   c. Antidepressants – Tricyclic Antidepressants.
   d. Barbiturates and benzodiazepines.
   e. Alcohol: ethanol, methanol.
   f. Paracetamol and salicylates.
   g. Non-steroidal anti-inflammatory drugs.
   h. Hydrocarbons: Petroleum products and PEG.
   i. Caustics: inorganic acids and alkali.
   j. Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings – Botulism and *C. Difficile* toxins.
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

a) CNS stimulants: amphetamine
b) Opioids
c) CNS depressants
d) Hallucinogens: LSD
e) Cannabis group
f) Tobacco

References:

a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad.

Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes:

1. Define various approaches to drug discovery.
2. Describe good clinical practices.
3. Practice ethical considerations in clinical research.
4. Compare regulatory environments in USA, Europe, and India.
5. Design clinical study documents.
6. Evaluate safety monitoring in clinical trials.

Course Content

1. Drug development process: Introduction Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP

    a) Sponsor
    b) Investigators
    c) Clinical research associate
    d) Auditors
    e) Contract research coordinators
    f) Regulatory authority

11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

References:

a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory: 3 Hrs. /Week

Course Outcomes:

1. Understand and summaries origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.
2. Recognize, interpret, and analyze the measurements of outcomes in pharmacoepidemiology.
3. Compare and contrast typical pharmacoepidemiologic study designs and explain their strengths and weaknesses.
4. Explain, compare, and analyze the features of Ad Hoc data sources and automated data systems for pharmacoepidemiology and pharmacovigilance purposes.
5. Explain and analyze the problems in the special applications of pharmacoepidemiological studies.
6. Identify, classify, compare, analyze, and evaluate the various methods of pharmacoeconomic studies.

Course Content

1.Pharmacoepidemiology:

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio and hazards ratio.

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, systematic reviews, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. Phrmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. Applications of Pharmacoeconomics Software and case studies

5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs. /Week

Course Outcomes:

1. Identify dose and dosing intervals in all age group patients.
2. Convert intravenous drug administration to oral drug administration.
3. Demonstrate the pharmacokinetics and pharmacodynamics of various drugs.
4. Practice dose adjustments in renal and hepatic impaired patients.
5. Summarize population pharmacokinetic data.
6. Interpret pharmacogenetic and PK-PD relation.

Course Content

1. **Introduction to Clinical pharmacokinetics.**
2. **Design of dosage regimens:**

   Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

3. **Pharmacokinetics of Drug Interaction:**
   a. Pharmacokinetic drug interactions
   b. Inhibition and Induction of Drug metabolism
   c. Inhibition of Biliary Excretion.

4. **Therapeutic Drug monitoring:**
   a. Introduction
   b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
   c. Indications for TDM. Protocol for TDM.
   d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
   e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

5. **Dosage adjustment in Renal and hepatic Disease.**
   a. Renal impairment
   b. Pharmacokinetic considerations
   c. General approach for dosage adjustment in Renal disease.
   d. Measurement of Glomerular Filtration rate and creatinine clearance.
   e. Dosage adjustment for uremic patients.
   f. Extracorporeal removal of drugs.
   g. Effect of Hepatic disease on pharmacokinetics.

6. **Population Pharmacokinetics.**
    a. Introduction to Bayesian Theory.
    b. Adaptive method or Dosing with feed back.
    c. Analysis of Population Pharmacokinetic Data.

7. **Pharmacogenetics**
    a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
    b. Genetic Polymorphism in Drug Transport and Drug Targets.
    c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

APPENDIX-B

(See regulation 9)

CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.
2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -

   a) are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948;
   b) have 300 bedded hospital attached to it.

I. Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

II. Speciality

a) Tertiary care hospitals are desirable
b) Medicine[compulsory], and any three specialization of the following
   1. Surgery
   2. Pediatrics
   3. Gynecology and obstetrics
   4. Psychiatry
   5. Skin and VD
   6. Orthopedics

III. Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

3) TEACHING STAFF REQUIREMENT

i. Staff Pattern: All faculty shall be full time. However, part time perceptors in hospital shall be allowed.

ii. Subject wise specialisation of the Teaching Staff:

S.No.	Subject	Specialisation required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics

17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

iii. Teaching Staff :

Department/Division	**Name of the post**	**No.**
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

iv. Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others:

Sl. No.	**CADRE**	**QUALIFICATIONS**	**EXPERIENCE**
1.	Lecturer	Basic degree in pharmacy (B.Pharm). Registration as a pharmacist under the Pharmacy Act. First Class Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	No minimum requirement.
2.	Assistant Professor	i. Basic degree in pharmacy (B.Pharm). ii. Registration as a pharmacist under the Pharmacy Act. iii. Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv. Ph.D. degree (with First Class degree either at Bachelor's or Master's level) in the appropriate branch of specialization in Pharmacy.	Three years' experience in Teaching or Research at the level of Lecturer or equivalent.

3.	Professor	i. Basic degree in pharmacy (B.Pharm). ii. ii) Registration as a pharmacist under the Pharmacy Act. iii. Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm). iv. Ph.D. degree (with first Class either at Bachelor's or Master's level) in appropriate branch of specialization in Pharmacy.	Ten years' experience in Teaching or Research. Out of which five years must be as Assistant Professor.
4.	Director or Principal or Head of institute	i.Basic degree in pharmacy (B.Pharm). ii.Registration as a pharmacist under the Pharmacy Act. iii.Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv.Ph.D. degree (with first Class degree either at Bachelor's or Master's level in the appropriate branch of specialization in Pharmacy.	i. Fifteen years' experience in Teaching or Research. ii. Out of which five years must be as Professor or above in Pharmacy. iii. Desirable: Administrative experience in responsible position. iv. The maximum age for holding the post shall be 65 years.

Note: If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

IV. Workload of Faculty: Professor – 8 hrs. per week Assistant Professor – 12 hrs. per week Lecturers – 16 hrs. per week

V. Training of Pharmacy Practice Faculty:

a)	Teaching staff will be trained as per the module prescribed by the Central Council.		
b)	Duration of training	–	Minimum 3 months.
c)	Training sites	–	Institutions running pharmacy practice or Programmes for atleast five years.
d)	Trainer	–	Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

4) NON-TEACHING STAFF:

Sl.No.	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm
2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor Degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning personnel	Adequate	---
11	Gardener	Adequate	---

5) ACCOMMODATION:

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores, etc.

At least two lecture halls alongwith eight laboratories as specified below should be provided for: —

1. Pharmaceutics and Pharmacokinetics Lab - 2
2. Life Science (Pharmacology, Physiology, Pathophysiology) - 2
3. Phytochemistry or Pharmaceutical Chemistry - 2
4. Pharmacy Practice - 2

Total = 8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS:

Department wise list of minimum equipment's

A. DEPARTMENT OF PHARMACOLOGY:

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01
5	Spygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone
11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01
15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10
20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01

30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

B. DEPARTMENT OF PHARMACOGNOSY:

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02
4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi	02
	channeled)	
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY:

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10
6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06
8	Muffle Furnace	01
9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Distillation Unit	02
2	Reflux flask and condenser single necked	20
3	Reflux flask and condenser double/ triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nesslers Cylinders	40

Note:

D. DEPARTMENT OF PHARMACEUTICS:

I. Equipment:

S.No	Name	Minimum required Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01
20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1liter capacity with speed control	05 EACH10
30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02
37	Conical Percolator (glass/copper/ stainless steel)	10

38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium,	05 each
	large)	
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department**.**

E. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY:

S.No.	Name	Minimum required Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01
16	Paper Electrophoresis Unit	01

17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

F. DEPARTMENT OF PHARMACY PRACTICE: Equipment:

S.No.	Name	Minimum required Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1
10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

1. Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.

2. Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and the department.

G. CENTRAL INSTRUMENTATION ROOM:

S.No.	Name	Minimum required Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Flourimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra-Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

APPENDIX-C

(See regulation 16)

INTERNSHIP

7. SPECIFIC OBJECTIVES:

(i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.

(ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.

(iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.

(iv) to demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.

(v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.

(vi) to communicate effectively with patients and the community.

8. OTHER DETAILS:

i. All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.

ii. Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

iii. Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a

period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

9. ASSESSMENT OF INTERNSHIP:

i. The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.

ii. Satisfactory completion of internship shall be determined on the basis of the following: -

(1) Proficiency of knowledge required for each case management SCORE 0-5

(2) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5

(3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5

(4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5

(5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

APPENDIX-D

(See regulation 17)

CONDITIONS TO BE FULFILLED BY THE EXAMINING AUTHORITY

1. The Examining Authority shall be a statutory Indian University constituted by the Central Government/State Government/Union Territory Administration. It shall ensure that discipline and decorum of the examinations are strictly observed at the examination centers.
2. It shall permit the Inspector or Inspectors of the Pharmacy Council of India to visit and inspect the examinations.
3. It shall provide:-
   (a) adequate rooms with necessary furniture for holding written examinations;
   (b) well-equipped laboratories for holding practical examinations;
   (c) an adequate number of qualified and responsible examiners and staff to conduct and invigilate the examinations; and
   (d) such other facilities as may be necessary for efficient and proper conduct of examinations.
4. It shall, if so required by a candidate, furnish the statement of marks secured by a candidate in the examinations after payment of prescribed fee, if any, to the Examining Authority.
5. It shall appoint examiners whose qualifications should be similar to those of the teachers in the respective subjects as shown in Appendix–B.
6. In pursuance of sub–section (3) of section 12 of the Pharmacy Act, 1948, the Examining Authority shall communicate to the Secretary, Pharmacy Council of India, not less than six weeks in advance the dates fixed for examinations, the time-table for such examinations, so as to enable the Council to arrange for inspection of the examinations.
7. The Examining Authority shall ensure that examiners for conducting examination for Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be persons possessing pharmacy qualification and are actually involved in the teaching of the Pharm.D. and Pharm.D. (Post Baccalaureate) programmes in an approved institution.

(ARCHNA MUDGAL)
Registrar-cum-Secretary
Pharmacy Council of India
New Delhi – 110002

Bharati Vidyapeeth
(Deemed to be University) Pune, India
Poona College of Pharmacy
Erandwane, Pune - 411 038
Website: https://www.bvuniversity.edu.in/pcp
Email: pcp@bharatividyapeeth.edu