BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE, INDIA
PhD Entrance Test – 2025
SECTION-II: Quality Assurance Techniques - 35 Marks

Section II	
1	**Study of concepts of cGMP covering the following aspects:** 1. Personnel 2. Building and facilities 3. Equipment 4. Quality Assurance & Quality control 5. Post Operational Activities 6. Manufacturing Operations and Control 7. Sterile Pharmaceutical Activities
2	**Pharmaceutical Validation covering the following aspects:** 1. Introduction to Pharmaceutical Validation. 2. Master Plans: Validation and calibration 3. Process validation 4. Qualification of Equipment 5. Cleaning validation and Facilities validation 6. Analytical Method Validation
3	**Quality management system** 1. Introduction to Quality 2. Basics of quality management 3. Six system inspection model 4. Developing quality culture 5. Quality in Manufacturing *6.* Statistical Process Control *7.* Documentation in pharmaceutical industry
4	**Audits in pharmaceutical industry** 1. Introduction to audit 2. Role of quality systems and audits in pharmaceutical manufacturing environment 3. Types of Audits 4. Vendor audit 5. Audit of operational areas (manufacturing, QC, engineering, Warehouse etc.)

References

1. Good Manufacturing Practices by S.H. Wills and J.R. Stoker, Marcker and Dekker incorporations.
2. Good Manufacturing Practices for Pharmaceuticals (6th Edn.) by Joseph D. Nally, Informa Healthcare Publication.
3. Selected International, GMP guidelines of various countries like UK, USA, Australia, South Africa. WHO. India. & ICH guide lines.
4. Pharmaceutical process validation by Robert Nash and A.H. Wacther, Marcel and Dekker Inc. Vol. 129.
5. Validation of pharmaceutical process (sterile products) by F.J. Carleton and J.P. Agalloco Marcel and Dekker Inc.
6. Quality planning and analysis. By J.M. Juran and F.M. Gryna Tata Mcgraw Hill India. 5th Edition.

7. Improving quality through planned experimentation By Moen.Tata Mcgraw Hill India.
8. Statistical Process Control by Grant. Tata Mcgraw Hill India.
9. Pharmaceutical statistics by S. Bolton; Marcel Dekker Inc.
10. Applied statistics in health care by Rao NSN, Murthy NS. Jaypee Brothers Medical Publishers. New Delhi.
11. Juran's quality handbook; Juran J.M. and Godfrey A.B. McGraw Hill.
12. Pharmaceutical Quality Assurance by M.A. Potdar Nirali Prakashan, Pune.
13. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
14. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsburyand Gil Bismuth, Interpharm/CRC, Boca Raton, London New York,Washington D.C.
15. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

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