BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE, INDIA
PhD Entrance Test – 2023
SECTION-II: Drug Regulatory Affairs - 35 Marks

1)	**GMP & GLP guidelines -** The Drugs and Cosmetics act, 1940 and Rules with emphasis on Good laboratory practices and requirements of premises and equipments (Schedule L-I), Good manufacturing practices for pharmaceutical products (Schedule M), Good manufacturing practices for homeopathic medicines (Schedule M-I), Requirements of factory premises for manufacture of cosmetics (Schedule M-II), Good manufacturing practices for Ayurvedic, Siddha and Unanni medicines (Schedule T).
2)	**ICH Guidelines for stability, analytical method validation**
3)	**Drug registration process & types - Preparation of CTD Document as per ICH**
4)	**Documentation, Audits & Inspections:** Master formula record, Batch packaging records, Standard operating procedure, Certificate of analysis, validation protocols, Stability protocol, Maintenance of records in Pharmaceutical industry. Audit types – Internal audit, external audit, regulatory audit. General process of audit planning.
5)	**Clinical trials Rules and Medical device rules**: Indian Regulations
6)	**Herbal Products:** Quality, safety and legislation for herbal products in India and USA

	References:	
1	Willing, Tuckerman and Hitchings, Good Manufacturing Practices for Pharmaceuticals	
2	Common Technical documents (ICH guidelines).	
3	WHO GMP guidelines	
4	Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.	
5	How to practice GLP by PP Sharma, Vandana Publications	
6	FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008	
7	www.who.int	
8	www.ich.org	
9	https://cdsco.gov.in	
10	www.fda.gov	

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