1711E1313

Candidate's Seat No :_____

M.Sc. Sem.-3 Examination

504

Pharma Science

November-2025

Time : 2-30 Hours] **[Max. Marks : 70**

Q1A	Discuss the key principles of GMP in pharmaceuticals.	7 Marks
Q1B	Elaborate on the GMP guidelines for equipment in pharmaceutical production, including calibration, validation (IQ, OQ, PQ), and cleaning validation to avoid contamination.	7 Marks
	OR	
Q1A	Explain the general provisions and requirements for organization and personnel under GMP for finished pharmaceutical products, including the importance of training and clear roles.	7 Marks
Q1B	Explain the packaging and labelling controls under GMP, including procedures to prevent mix-ups, reconciliation of quantities, and tamper-evident packaging for OTC drugs.	7 Marks
Q2A	What are the key roles and responsibilities of QA personnel in ensuring GLP compliance?	7 Marks
Q2B	How do computers enhance efficiency and accuracy in data handling, record maintenance, and analysis under GLP? Explain in detail.	7 Marks
	OR	
Q2A	Write a short note on Standard Operating Procedure (SOP), its format and essential components required for it.	7 Marks
Q2B	Write differences between QC v/s QA inpharmaceutical studies.	7 Marks
Q3A	Discuss the harmonization of regulatory requirements through ICH activities, including the structure of ICH guidelines (Quality, Safety, Efficacy, and Multidisciplinary).	7 Marks
Q3B	Discuss the Indian regulatory framework under CDSCO, including NDCTR 2019, Schedule M, and comparisons with ICH-GCP in terms of ethics approval and informed consent.	7 Marks
	OR	
Q3A	Describe the US FDA regulatory framework for finished pharmaceutical products, including 21 CFR Part 211 provisions for production controls and labelling.	7 Marks
Q3B	Outline the principles of Good Clinical Practices (GCP) as per ICH E6(R2), including sponsor responsibilities, ethics committee roles, and data integrity.	7 Marks

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E1313-2

Q4A	Discuss the basic concepts and objectives of stability studies in pharmaceuticals, including their role in predicting shelf life and ensuring product quality.	7 Marks
Q4B	Elaborate on the importance of accelerated stability studies, including the use of Arrhenius equation for extrapolation to real-time conditions.	7 Marks
	OR	
Q4A	Describe the effects of environmental and processing factors (e.g., light, pH, temperature, moisture) on formulation stability, and techniques for product stabilization.	7 Marks
Q4B	Discuss bracketing and matrixing designs in stability testing, including their applications, justifications, and limitations for optimizing resource use.	7 Marks
Q5	**Answer the following questions (Any Seven)**	**14 Marks**
I	Name the key regulatory bodies overseeing GMP globally.	2 Marks
II	Define Quality Management System (QMS) in the context of GMP.	2 Marks
III	Explain the role of SOPs in GMP manufacturing.	2 Marks
IV	What is GMP? Give an importance of it inpharma industry.	2 Marks
V	What does the acronym MSI stand for in the context of GLP, and what is its purpose in a test facility?	2 Marks
VI	What is the full form of GMP and GLP?	2 Marks
VII	Name the four categories of ICH guidelines.	2 Marks
VII	What is the role of the Ethics Committee (EC) in GCP?	2 Marks
IX	What is the difference between ICH-GCP and Indian NDCTR regarding compensation?	2 Marks
X	Why are accelerated stability studies conducted?	2 Marks
XI	How does pH affect drug stability?	2 Marks
XII	What is bracketing in stability study design?	2 Marks

BEST OF LUCK