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2811E837

Candidate's Seat No : _____

M.Sc Sem-3 Examination

504

Pharma Science (EA)

November-2024

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

Q1A	What are the GMP provisions for packaging and labelling in pharmaceuticals? How do these provisions ensure product safety and compliance with regulatory standards?	7 Marks
Q1B	Discuss the key GMP requirements for finished pharmaceutical products.	7 Marks
	OR	
Q1A	Describe the GMP guidelines related to building and facilities in pharmaceutical manufacturing. How do these guidelines ensure the prevention of contamination and ensure a clean production environment?	7 Marks
Q1B	Discuss the role of laboratory control and record-keeping in GMP. How does proper documentation and control of records contribute to ensuring product quality and regulatory compliance?	7 Marks
Q2A	List key responsibilities of Quality Assurance (QA) personnel in ensuring GLP compliance.	7 Marks
Q2B	Explain the format and essential components required for writing a Standard Operating Procedure (SOP).	7 Marks
	OR	
Q2A	Explain the difference between Quality Control (QC) and Quality Assurance (QA) in pharmaceutical studies.	7 Marks
Q2B	Explain the role of computers in a Quality Control laboratory. How do they enhance efficiency and accuracy in data handling, record maintenance, and analysis under Good Laboratory Practices?	7 Marks
Q3A	Describe the Efficacy guidelines according to ICH forPharmacovigilance E2A to E2F.	7 Marks
Q3B	Write a detailed note on the safety guidelines given by the ICH (S1 to S13).	7 Marks
	OR	
Q3A	Describe the ICH Guidelines regarding (Q7) Good Manufacturing Practice (GMP) for the manufacturing of Active Pharmaceutical Ingredients (APIs)	7 Marks
Q3B	Discuss the regulatory requirements for the development and approval of extended-release pharmaceutical products.	7 Marks
Q4A	Write a detailed note on the basic concepts and objectives of the stability study.	7 Marks
Q4B	Write a detailed note on the impurities and photostability in stability testing.	7 Marks

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	OR	
Q4A	Describe the stability testing procedure for pharmaceutical formulations.	7 Marks
Q4B	Examine the effects of various environmental and processing factors (e.g., light, pH, temperature) on the stability of pharmaceutical formulations. What techniques can be used to stabilize products against these factors?	7 Marks
Q5	**Answer the following questions (Any Seven)**	**14 Marks**
I	What does GMP stand for, and why is it important in the drug industry?	2 Marks
II	Name two critical factors that GMP guidelines focus on for equipment used in drug manufacturing.	2 Marks
III	What is meant by the term "finished product" in the context of GMP in pharmaceuticals?	2 Marks
IV	What is the significance of accurate record-keeping in a GLP-compliant laboratory?	2 Marks
V	How do GLP guidelines apply to the control and maintenance of animal houses in non-clinical research?	2 Marks
VI	What does the acronym MSI stand for in the context of GLP, and what is its purpose in a test facility?	2 Marks
VII	Quality risk management comes under which ICH guideline?	2 Marks
VII	Clinical trials come under which ICH guideline?	2 Marks
IX	Write the full form of MedDRA	2 Marks
X	Write two methods of predicting the self-life of pharmaceutical formulations.	2 Marks
XI	Name the ICH guideline for stability testing in pharmaceutical formulations.	2 Marks
XII	Describe the climate zone for stability testing.	2 Marks

BEST OF LUCK