JHARKHAND Rai University
RANCHI

PRACTICE SET FOR SUBJECTIVE QUESTIONS
End Semester (Semester VII) Examination, Dec-2025

Program: B. Pharm

Subject: Industrial Pharmacy II (Theory)

Subject Code : BP702T

Unit I			
S No.	**Questions**	**CO**	**Bloom's Taxonomy Level**
Section II			**Questions for 5 marks**
1	Define pilot plant scale-up and state its main purpose in pharmaceutical manufacturing.	CO1	Remember
2	Describe three general considerations that must be addressed before scaling up a batch in a pilot plant (e.g., personnel, space, raw materials).	CO1	Remember
3	Explain why personnel requirements are significant for successful pilot plant scale-up in the pharmaceutical industry.	CO1	Understand
4	Name the main documentation required during pilot plant scale-up trials.	CO1	Remember
5	Compare the scale-up challenges between solid dosage forms and liquid orals, giving one example for each.	CO1	Understand
6	Describe how SUPAC guidelines help ensure quality during pharmaceutical process scale-up.	CO1	Understand
7	Discuss the role of platform technology in improving the efficiency and flexibility of pilot plant operations.	CO1	Understand
Section III			**Questions for 10 marks**
8	Create a comprehensive action plan for scaling up a new solid dosage formulation from laboratory scale to pilot plant, considering personnel requirements, space planning, raw material logistics, equipment selection, documentation workflow, and risk management for process failures. Justify your choices with references to current industry guidelines and scale-up challenges.	CO1	Create
9	Develop an integrated strategy for documenting and controlling scale-up operations for liquid orals and semi-solid dosage forms in a pharmaceutical pilot plant. Address key checkpoints such as material handling, process validation, critical equipment specification, documentation standards, and coordination between R&D, manufacturing, and quality assurance teams.	CO1	Create
10	Design a guideline interpretation framework to help a pharmaceutical company implement SUPAC recommendations and platform technology in streamlining pilot plant scale-up. Critically evaluate how this approach enhances efficiency, quality assurance, post-approval change management, and regulatory compliance in various dosage form manufacturing.	CO1	Create

Unit II			
S No.	**Questions**	**CO**	**Bloom's Taxonomy Level**
Section II			**Questions for 5 marks**
11	Define technology transfer (TT) according to WHO guidelines.	CO2	Remember
12	List the main documentation requirements during a pharmaceutical technology transfer project.	CO2	Remember
13	Explain the role of quality risk management in technology transfer, and identify one method used to assess risks.	CO2	Understand
14	Discuss two key differences between transfer of APIs and excipients in the granularity of TT process.	CO2	Understand
15	Describe the purpose of analytical method transfer during technology transfer in pharmaceutical manufacturing.	CO2	Understand
16	Summarize the responsibilities of a technology transfer team in ensuring successful transfer from R&D to production.	CO2	Understand
Section III			**Questions for 10 marks**
17	Design a comprehensive technology transfer protocol for the scale-up of a new pharmaceutical product, integrating WHO guidelines. Address all critical stages, including risk assessment, process and cleaning transfer, documentation, qualification, analytical method transfer, and regulatory compliance. Justify your workflow with examples from successful industry transfer cases.	CO2	Create
18	Construct a documentation framework for pharmaceutical technology transfer that ensures compliance with WHO guidelines and regulatory expectations. Your framework should cover transfer plans, validation studies, analytical method protocols, qualification reports, change management, legal agreements, and cross-site communication. Critically assess how thorough documentation supports risk management, transparency, and successful knowledge transfer in real transfer scenarios.	CO2	Create
19	Draft a stepwise roadmap for the commercialization of a transferred pharmaceutical process, highlighting the roles of Indian TT agencies (APCTD, NRDC, TIFAC, BCIL, and TBSE/SIDBI). Include critical TT-related documentation, risk management structures, and stakeholder responsibilities. Critically analyze common challenges in the Indian context and propose solutions based on current regulatory and market realities.	CO2	Create
Unit III			
S No.	**Questions**	**CO**	**Bloom's Taxonomy Level**
Section II			**Questions for 5 marks**
20	Define regulatory affairs in the context of the pharmaceutical industry and state its primary objective.	CO3	Remember
21	Discuss the importance of biostatistics in pharmaceutical product development and FDA submissions.	CO3	Understand
22	List two major responsibilities of regulatory affairs professionals during pharmaceutical product development.	CO3	Remember
23	Name any two key regulatory authorities involved in global drug approval processes.	CO3	Remember
24	Describe the general considerations and significance of an Investigator's Brochure (IB) in the context of clinical research and	CO3	Understand

	regulatory submissions.		
25	Explain the role of Drug Development Teams in the regulatory approval process for new pharmaceutical products.	CO3	Understand
Section III			**Questions for 10 marks**
26	Create a detailed IND and NDA submission plan for a new drug candidate, outlining core components, workflow, and how you would resolve typical regulatory hurdles during approval.	CO3	Apply
27	Enumerate with explanation a global regulatory strategy for launching a generic drug, addressing dossier adaptation, bioequivalence, and pharmacovigilance for the US, EU, and Indian authorities.	CO3	Apply
28	Given incomplete biostatistical data in a clinical trial, develop a corrective action plan to achieve FDA submission-readiness. Explain coordination among regulatory, development, and clinical teams to ensure compliance.	CO3	Apply
Unit IV			
S No.	**Questions**	**CO**	**Bloom's Taxonomy Level**
Section II			**Questions for 5 marks**
29	Define Total Quality Management (TQM) and state two key features relevant to pharmaceuticals.	CO4	Remember
30	List three fundamental principles of Quality by Design (QbD).	CO4	Understand
31	What is Six Sigma and what is its main objective in pharmaceutical manufacturing?	CO4	Understand
32	Explain the term Out of Specifications (OOS) and discuss its impact on product quality.	CO4	Understand
33	Describe the purpose and significance of ISO 9000 and ISO 14000 certifications for pharmaceutical companies.	CO4	Remember
34	Discuss the role of NABL accreditation in enhancing credibility of laboratories within the pharmaceutical sector.	CO4	Understand
35	Illustrate the principles of Good Laboratory Practice (GLP) and its importance for pharmaceutical research and development.	CO4	Understand
Section III			**Questions for 10 marks**
36	Design a company-wide strategy to implement Total Quality Management (TQM), integrating principles of Six Sigma and Quality by Design (QbD). Outline how your plan would address continuous improvement, regulatory compliance, and staff engagement.	CO4	Create
37	Develop a robust protocol for Out of Specification (OOS) investigations and change control, ensuring alignment with ISO 9000/14000 standards, NABL, and GLP requirements. Demonstrate how effective documentation and cross-functional collaboration support compliance and product quality.	CO4	Create
38	Analyze the effectiveness of integrating Six Sigma with existing TQM practices in a pharmaceutical company. Identify key benefits, limitations, and provide examples of measurable improvements in quality or efficiency.	CO4	Analyze
Unit V			
S No.	**Questions**	**CO**	**Bloom's Taxonomy Level**
Section II			**Questions for 5 marks**
39	Define CDSCO and explain its primary function in drug regulation.	CO5	Remember

40	List two regulatory responsibilities of State Licensing Authorities in India.	CO5	Remember
41	Describe the role of COPP in combating counterfeit medicines and ensuring product authenticity.	CO5	Understand
42	Identify three essential documents required to obtain COPP in India.	CO5	Remember
43	Name two types of pharmaceutical products for which COPP can be issued.	CO5	Remember
44	Explain how CDSCO coordinates with State Licensing Authorities for drug approvals in India.	CO5	Understand
45	Discuss the steps involved in the approval process for a new drug in India according to CDSCO regulations.	CO5	Understand
46	What is a Certificate of Pharmaceutical Product (COPP) and why is it needed for exports?	CO5	Understand
Section III			**Questions for 10 marks**
47	Analyze the organizational structure and key responsibilities of CDSCO compared to State Licensing Authorities. How do their roles complement each other in regulating pharmaceutical products in India?	CO5	Analyze
48	Create a compliance roadmap for a company planning to launch a new drug in India, integrating regulatory requirements, COPP application, and interagency coordination. Justify your approach in terms of efficiency, patient safety, and regulatory success.	CO5	Create
49	Examine the process for obtaining a Certificate of Pharmaceutical Product (COPP) through CDSCO. Analyze the regulatory steps, documentation, and joint inspections involved, highlighting challenges manufacturers may face.	CO5	Analyze
50	Analyze the approval procedure for new drugs in India, from IND application through NDA submission. Discuss regulatory checkpoints, documentation, and post-approval surveillance, emphasizing the role of both CDSCO and State Authorities in risk management and public health.	CO5	Analyze

Course Learning Objective (CLO)

- CLO 1: To develop a comprehensive understanding of scaling up pharmaceutical formulations.
- CLO 2: To understand WHO guidelines for pharmaceutical technology transfer focus on systematically transferring documented knowledge and expertise
- CLO 3: Will develop comprehensive knowledge and skills in pharmaceutical regulatory affairs, including understanding regulatory authorities
- CLO 4: Will understand key quality concepts such as Total Quality Management, Quality by Design, Six Sigma, OOS, Change Control, and ISO standards, and to apply these principles
- CLO 5: Will be able to ensure compliance and successful pharmaceutical product registration.

Summary sheet

CO WISE

CO	Q. WISE	MARKS
CO1	1, 2, 3, 4, 5, 6, 7, 8, 9, 10	65
CO2	11, 12, 13, 14, 15, 16, 17, 18, 19	60
CO3	20, 21, 22, 23, 24, 25, 26, 27, 28	60
CO4	29, 30, 31, 32, 33, 34, 35, 36, 37, 38	65
CO5	39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50	80
	total	330

UNIT WISE

UNIT	Q. WISE	MARKS
UNIT 1	1, 2, 3, 4, 5, 6, 7, 8, 9, 10	65
UNIT 2	11, 12, 13, 14, 15, 16, 17, 18, 19	60
UNIT 3	20, 21, 22, 23, 24, 25, 26, 27, 28	60
UNIT 4	29, 30, 31, 32, 33, 34, 35, 36, 37, 38	65
UNIT 5	39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50	80
	total	330

Blooms taxonomy level (wise)

UNIT	Q. WISE	MARKS
LOT	1, 2, 3, 4, 5, 6, 7, 11, 12, 13, 14, 15, 16, 20, 21, 22, 23, 24, 25, 29, 30, 31, 32, 33, 34, 35, 39, 40, 41, 42, 43, 44, 45, 46	170
HOT	8, 9, 10, 17, 18, 19, 26, 27, 28, 36, 37, 38, 47, 48, 49, 50	160
	Total	330

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Disclaimer: -This is a Practice Set. The Question in End term examination will differ from the Practice Set. This Practice Set is meant for practice only.