Name: Enrolment No:	

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, December 2022

Course: Industrial Pharmacy II **Semester: III**
Program: B. Pharm. **Time: 03 hrs.**
Course Code: BP702T **Max. Marks: 75**
Instructions: All the sections are compulsory.

SECTION A

S. No.	CO		Marks
		Answer all the questions.	**20**
1.	**CO1**	The filling method of a pharmaceutical liquid depends on the following factors _____ . A. Viscosity of the liquid B. Surface tension of the liquid C. Compatibility with material of machine D. All of the above	**1**
2.	**CO1**	Define pilot plant.	**1**
3.	**CO1**	Which of the following is not an objective of pilot-plant? A. Avoidance of the problems associated with the scale-up. B. Evaluation and Validation for process and equipment. C. Manufacturing of lab-scale batches. D. To identify the critical features of the process	**1**
4.	**CO1**	Chronological order of mixing of excipient can also impact the quality and performance of formulation. A. True B. False	**1**
5.	**CO2**	Transfer of Cleaning protocols is an important part of Technology Transfer process. A. True B. False	**1**
6.	**CO2**	What is BCIL?	**1**
7.	**CO2**	What is Technology Transfer?	**1**
8.	**CO2**	Define Corrective action.	**1**
9.	**CO3**	Define Design space.	**1**
10.	**CO3**	Define In process controls.	**1**
11.	**CO3**	What is NDA?	**1**
12.	**CO3**	What is IND?	
13.	**CO4**	Define quality attributes for quality by design.	**1**
14.	**CO4**	Quality management system deals with_____. A. Quality for their products and services B. Safety for their products and services C. Quality and safety for their products D. Quality and safety for their products and services	**1**

15.	**CO4**	Significant reduction in number of trial batches is one of the advantages of quality by design approach. A. True B. False	**1**
16.	**CO4**	ICH guidelines involve _____ guidelines. A. Quality and safety B. Quality and control C. Quality, Safety, efficacy and Multidisciplinary D. Safety and efficacy	**1**
17.	**CO5**	Which of following is certification system for laboratory accreditation? A. NABL B. WHO C. ISO D. GMP	**1**
18.	**CO5**	There are _____ Phases of clinical trials . A. 2 B. 3 C. 4 D. 5	**1**
19.	**CO5**	Enlist any two functions CDSCO.	**1**
20.	**CO5**	The headquarter of CDSCO is located at _____. A. Ghaziabad B. Ahmedabad C. Mumbai D. Kolkata	**1**
		SECTION B	
Answer any two questions of the following.			**20**
1.	**CO1**	Write a short note on general consideration of pilot plant techniques.	**10**
2.	**CO2**	Discuss the role of a. IQ,OQ and PQ in Technology Transfer. b. Regulatory affairs professionals	**5+5**
3.	**CO3**	Discuss the roles and responsibilities of a. Sending Unit (SU) b. Receiving Unit (RU)	**5+5**
		SECTION C	
Answer any seven questions of the following.			**35**
1.	**CO5**	Enlist the functions of state licensing authorities.	**5**
2.	**CO1**	Enlist the advantages and disadvantages of pilot plants.	**5**
3.	**CO3**	Write a note on Technology transfer agencies in India.	**5**
4.	**CO5**	Give the brief account of organization of CDSCO.	**5**
5.	**CO4**	Explain the scope of quality management system in pharmacy.	**5**
6.	**CO2**	Discuss legal issues that may arise during a Technology transfer process.	**5**
7.	**CO5**	Write a short note on drug testing laboratories.	**5**
8.	**CO4**	Write the significance quality by design	**5**

9.	**CO4**	Explain in brief the steps involved in change control.	**5**
		Total	**75**