Name: **Enrolment No:**	UPES UNIVERSITY WITH A PURPOSE

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Theory Examination, May 2022

Course: Quality Assurance **Semester: VI**
Program: B. Pharm. **Time 03 hrs.**
Course Code: BP606T **Max. Marks: 75**
Instructions:

SECTION A

I	**CO**	**Multiple Choice Questions or Objective type Questions (20x1)**	**Marks**
1	CO1	Which ICH guideline discuss about the validation studies a. Q1 b. Q2. c. Q3 d. Q5	1
2	CO1	What do you mean by CAPA	1
3	CO1	Which ISO guideline series discuss details of Quality management systems a. ISO 17025 b. ISO 9000 c. ISO 14000 d. ISO 17000	1
4	CO5	Class 100 is relatively more clean room Class 1000. True/False	1
5	CO1	Which ICH guideline discuss about the photostability studies is given a. Q1a b. Q1b c. Q1c d. Q1d	1
6	CO4	What do you mean by class 3 product recall	1
7	CO5	Give temperature conditions for accelerated stability studies	1
8	CO1	Define LoQ	1
9	CO4	Write the relation between signal and noise in measuring Limit of detection	1
10	CO4	Give any two parameters which require calibration	1
11	CO2	Alkaline error and asymmetric potential is associated with which instrument a. HPLC b. UV spectrophotometer c. pH meter d. Gas Chromatography	1
12	CO1	What should be the preferable range of slope for pH meter	1

13	CO1	Good Manufacturing Practices is mentioned in which ICH guideline a. Q4 b. Q2 c. Q7 d. Q5	1
14	CO5	_____ document contain all information about the manufacturing of the product	1
15	CO3	_____ is a step by step instructions compiled by an organization to help workers carry out routine operations	1
16	CO1	What do you mean by HVAC	1
17	CO3	Market product complaints are handled by Quality Assurance department. True/False	1
18	CO2	Give an example of secondary packaging material	1
19	CO1	Define term cross contamination	1
20	CO1	Define the term assay	1
SECTION B			
Long Answers (Answer two out of 3) 2x10			20
II 1.	CO5	What is Master formula Record. Write its contents and discuss its significance.	10
2.	CO4	Write a SOP to perform a Drying in Hot air Oven	10
3.	CO1	Define Validation. Write about different validation parameters	10
SECTION C			
Short Answers (Answer 7 out of 9) 7X5			35
III 1.	CO2	Write the significance of Quality Audits	5
2.	CO1	What are different elements of quality by design approach	5
3.	CO4	Write different steps to purchase raw materials for manufacturing in a pharmaceutical industry	5
4.	CO4	What do you understand by installation qualification	5
5.	CO5	What are the reasons for a product recall	5
6.	CO5	Describe few parameters with respect to premises of an industry to assure quality	5
7.	CO5	A student performs an experiment on UV spectrophotometer and obtain following readings for absorbance. Calculate the range for linearity of the given data Conc Abs 1. 1ppm – 0.1 2. 2ppm – 0.2 3. 3ppm – 0.3 4. 4ppm – 0.4	5

		5. 5ppm - 0.5 6. 6ppm – 0.9 7. 7ppm – 1.03 8. 8ppm – 1.15 9. 9ppm – 1.17	
8.	CO5	Write about difference in roles of QC and QA department	5
9.	CO1	Write 5 points mentioned in ISO 9001 guideline	5
		Total	75