


Name:			
Enrolment No:			
UPES End Semester Examination, December 2024			
Course: Industrial Pharmacy - II Program: B.Pharm Course Code: BP 702T		Semester: VII Duration : 03 Hours Max. Marks: 75	
Instructions: Read the questions carefully and attempt as per the marks assigned.			
SECTION A (20Qx1M=20 Marks)			
S. No.	Attempt all questions	Marks	COs
Q 1	QRM deals with	1	CO1
Q 2	Scale up of a formulation should be of final commercial scale batch size. a) 1/1000 th b) 1/100 th c) 1/10 th d) 1/10000 th	1	CO1
Q 3	Master formula card include following except : a) Product name b) Stability profile of drug c) Generic name d) Product strength	1	CO2
Q 4	SUPAC guidelines require submission of bioequivalence data for which level of change? a) Level 1 b) Level 2 c) Level 3 d) Level 4	1	CO2
Q 5	Define acceptance criteria in technology transfer.	1	CO2
Q 6	"Granularity" in the technology transfer process refer to - a) The specific types of equipment used b) The level of detail in data and process information c) The speed of the transfer process d) The number of products being transferred	1	CO2
Q 7	Indian government organization is primarily involved in licensing patents and technologies is a) APCTT b) NRDC c) BCIL d) SIDBI	1	CO2
Q 8	Which of the following document serves as the primary reference for the recipient during technology transfer ? a) Process Validation Plan b) Technology Transfer Protocol c) Master Batch Record d) Quality Agreement	1	CO2
Q 9	The process of NDA takes years. a) 5 b) 10 c) 12 d) 15	1	CO3
Q 10	How many zonal offices does CDSCO currently have? a) 4 b) 6 c) 8 d) 10	1	CO3
Q 11	DTAB stands for	1	CO3
Q 12	"Guidelines for Bioavailability & Bioequivalence Studies" mentioned in Schedule of Act.	1	CO3
Q 13	Six sigma allows for 6.4 defects per million opportunities for a defect to occur. True/False	1	CO4

Q 14	Who is the present DCGI of India?	1	CO4
Q 15	GLP is an FDA regulation which is accepted and approved by a)OECD b) CDER c) CBER d) DCC	1	CO4
Q 16	TQM deals with “prevention of defects rather than detection of defects”. True/False	1	CO4
Q 17	ISO 14000 focuses on : a) Quality risk management b) Environmental management systems c) Total quality managements d) Financial managements	1	CO4
Q 18	Fault tree analysis is one of the approaches for total quality management. True/False	1	CO4
Q 19	ICH stands for	1	CO5
Q 20	CoPP deals with	1	CO5
SECTION B (20 Marks) (2Qx10M=20 Marks)			
Attempt 2 Questions out of 3			
Q 1	Discuss in detail about scale up considerations for solid dosage forms emphasizing any two of the following processes: a) dry blending for direct compression, b) slugging, c) drying.	5+5	CO1
Q 2	Explain the IND application process, including a) flow chart, b) objectives, c) criteria for application, and d) key information included in the application.	5+1+2+2	CO3
Q 3	Quality management systems are critical for preventing variation and maintaining the desired specifications in the process. Support the above statement by focusing on QbD and six sigma concepts.	10	CO4
SECTION-C (35 Marks) (7Qx5M=35 Marks)			
Attempt 7 Questions out of 9			
Q 1	Discuss SUPAC guideline for immediate release tablets (SUPAC-IR) in brief.	5	CO1
Q 2	What is the importance of analytical method transfer in technology transfer. Differentiate between any 4 basic responsibilities of sending unit and receiving unit.	1+4	CO2
Q 3	Write about any two technology transfer agencies in India in brief.	5	CO2
Q 4	Explain designing of platform technology with suitable examples.	4+1	CO3
Q 5	What is the significance of risk management in QRM? Describe event tree analysis approach in detail.	1+4	CO4
Q 6	Discuss DMAIC methodology.	5	CO4
Q 7	The customer specification limit of room temperature for a process is 26°C but the capability of the facility for average room temperature is approximately 22 °C with a standard deviation of 1.5°C. Calculate Z-value for the process.	5	CO4
Q 8	Write the name (not acronym) of regulatory authorities for regulation of medicines and medical devices in following countries : a) Europe, b) India, c) Canada, d) Japan, e) Australia	5	CO5
Q 9	Discuss various functions of CDSCO.	5	CO5