

Name:			
Enrolment No:			
UPES End Semester Examination, December 2025 Course: Industrial Pharmacy - II Semester: VII Program: B.Pharm Duration : 03 Hours Course Code: BP 702T Max. Marks: 75			
Instructions: Read the questions carefully and attempt as per the marks assigned			
SECTION A (20Qx1M=20 Marks)			
S. No.	Multiple choice questions/Short answers	Marks	COs
Q 1	Batch size during the scale up of a formulation should be of its final commercial scale batch. a) 1/1000 th b) 1/100 th c) 1/10 th d) 1/10000 th	1	CO1
Q 2	Enlist any 2 applications of platform technology.	1	CO1
Q 3	ICH stands for	1	CO1
Q 4	Master formula card includes following except : a) Product name b) Stability profile of drug c) Generic name d) Product strength	1	CO2
Q 5	According to the SUPAC guidelines, <i>in vivo</i> bioequivalence documentation is required in which level of changes?	1	CO1
Q 6	Which of the following is most widely used stainless steel type in pharmaceutical industries? a) Type 316 b) Type 317 c) Type 318 d) Type 319	1	CO2
Q 7	Module 4 of CTD includes: a) Quality data b) Non-clinical data c) Clinical study reports d) None of the above	1	CO2
Q 8	"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 9	Event tree analysis is one of the methodology for a) Quality risk management b) Total quality management c) Technology transfer d) Pilot plant scale up	1	CO2
Q 10	BE studies are requirement for process. a) IND b) NDA c) ANDA d) TQM	1	CO3
Q 11	21CFR Part deals with IND applications. a) 311 b) 312 c) 313 d) 314	1	CO3
Q 12	Phase 4 of clinical trial studies are conducted : a) Before IND approval b) Only in healthy volunteers c) After marketing approval d) Only when safety concerns arise	1	CO3

Q 13	ISO 14000 focuses on: a) Quality risk management b) Environmental management systems c) Total quality managements d) Financial managements	1	CO4
Q 14	Which statement best differentiates QTPP from CPPs in tablet manufacturing? a) QTPP focuses on manufacturing steps, whereas CPPs focus on the final product's specifications b) QTPP is part of GMP requirements, whereas CPPs belong to GLP c) QTPP describes desired product performance, while CPPs describe process conditions needed to achieve those attributes d) QTPP varies daily based on batch size, while CPPs are fixed	1	CO4
Q 15	Which regulatory guideline focuses on QbD? a) ICH Q8 b) ICH Q9 c) ICH Q10 d) ICH Q12	1	CO4
Q 16	Six sigma concept includes a) Define, Measure, Analyze, Improve and Control b) Design, Measure, Analyze, Improve and Control c) Define, Manage, Analyze, Improve and Control d) Design, Manage, Analyze, Improve and Control	1	CO4
Q 17	NABL stands for	1	CO4
Q 18	Who is the current DCGI of India?	1	CO5
Q 19	What is the total number of Central Drug Testing Laboratories operated under CDSCO? a) 11 b) 9 c) 7 d) 1	1	CO5
Q 20	CoPP stands for	1	CO5
SECTION B (20 Marks) (2Qx10M=20 Marks) Attempt 2 Question out of 3			
Q 1	a) Highlight the core functions carried out by CDSCO in India's drug regulatory framework. b) Write the name of regulatory authorities of following countries/regions : USA, Australia, Europe, Japan, UK.	5+5	CO5
Q 2	a) Classify the types of IND with appropriate examples. b) Outline the procedure of an IND submitted to the FDA with the help of flow diagram.	5+5	CO3
Q 3	Discuss the factors that must be evaluated during the pilot-plant scale-up of liquid orals to ensure process reproducibility at commercial scale.	10	CO1
SECTION-C (35 Marks) (7Qx5M=35 Marks) Attempt 7 Question out of 9			
Q 1	Describe the major stages involved in the drug development process.	5	CO3
Q 2	Outline the variations in study populations and trial focus as clinical development progresses from Phase 1 to Phase 3.	5	CO3
Q 3	Differentiate between an IND, an NDA and an ANDA in terms of purpose.	5	CO3
Q 4	Briefly discuss the roles and functions of following technology-transfer agencies: APCTT and NRDC.	5	CO2
Q 5	Illustrate the CTD framework in a simple diagram highlighting all modules.	5	CO2
Q 6	Outline the conceptual design of platform technology and provide an illustrative example.	5	CO1
Q 7	Explain the PDCA cycle and its relevance to quality improvement.	5	CO4

Q 8	Classify medical devices under regulatory guidelines and provide examples of each class.	5	CO5
Q 9	Explain the applications of DMAIC methodology as quality management system.	5	CO4