UPES **Enrolment No:** UPES **End Semester Examination, December 2023 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. Attempt all questions Marks COs Which of the following is not involved in quality risk management? **Q1** b) Risk identification 1 **CO3** a) Risk assessment c) Risk analysis c) Risk retardation **O** 2 The process of NDA takes years. **CO3** 1 a) 5 c) 12 d) 15 b) 10 Q 3 Six sigma concept includes **CO4** a) Define, Measure, Analyze, Improve and Control b) Design, Measure, Analyze, Improve and Control 1 c) Define, Manage, Analyze, Improve and Control d) Design, Manage, Analyze, Improve and Control Enlist the 2 types of technology transfer process. 04 1 **CO2** ISO 14000 deals with..... **Q**5 **CO4** 1 **Q**6 SIDBI stands for 1 **CO2** Q7 DCC stands for 1 **CO5** Identification of critical elements of a process is known as **CO2** 08 1 a) Design spacing b) Gap analysis c) IPOC d) Validation Which of the following is certification system for laboratory accreditation? Q 9 **CO4** 1 b) WHO c) NABL d) GMP a) ISO Non-clinical development is also known as Q 10 **CO4** a) Post clinical development b) Clinical development 1 d) None of the above c) Pre-clinical development TQM deals with "prevention of defects rather than detection of defects". Q 11 **CO4** 1 **True/False** Master formula card include following except : Q 12 **CO2** a) Product name b) Stability profile of drug 1 d) Product strength c) Generic name BE studies is a requirement for process. **Q 13 CO3** 1 b) NDA c) ANDA a) IND d) TQM "Guidelines for Bioavailability & Bioequivalence Studies" mentioned in Q 14 **CO3** Schedule of Drug and Cosmetics Act. 1

Name:

a) M

b) Y

c) P

d) H

Q 15	There are phases of clinical trials.	1	CO5
	a) 1 b) 2 c) 3 d) 4	1	
Q 16		1	CO4
Q 17	Scale-up of a formulation should be 1/10 th of the final commercial scale batch size. True/False	1	CO1
Q 18	Fault tree analysis is one of the approaches undera) Total quality managementb) Quality risk managementc) Six sigma conceptd) CoPP	1	CO4
Q 19	Define acceptance criteria in technology transfer.	1	CO2
Q 20	Six sigma allows for 3.4 defects per million opportunities for a defect to occur. True/False	1	CO4
SECTION B (20 Marks)			
(2Qx10M=20 Marks)			
Attempt 2 Questions out of 3			
Q 1	Illustrate the process of investigational new drug application in detail including a flow chart with focus on objectives, criteria for application and information included.	5+1+2 +2	CO3
Q 2	Discuss in detail about various considerations in pilot-plant scale-up of solid dosage forms.	10	CO1
Q 3	Discuss technology transfer protocol in detail. What should be included in analytical method transfer protocol? Explain with emphasis on SU and RU responsibilities.	4+6	CO2
SECTION-C (35 Marks)			
(7Qx5M=35 Marks)			
Attempt 7 Questions out of 9			
Q 1	Enlist 2 methodologies of six sigma concept. Briefly discuss any one of them.	1+4	CO4
Q 2	The upper specification limit of RH for a process is 43% but the capability of the facility for average RH is approximately 40% with a standard deviation of 1.5%. Calculate Z-value for the process.	5	CO4
Q 3	What is the role of technology transfer agencies? Write about any two TT agencies in brief.	1+4	CO2
Q 4	Discuss SUPAC guideline for immediate release tablets in brief.	5	CO1
Q 5	Write a short note on designing of platform technology with suitable examples.	4+1	CO1
Q 6	Discuss various functions of CDSCO.	5	CO5
Q 7	Enlist any 2 risk management methodologies. Describe any one in detail.	1+4	CO4
Q 8	Explain various phases involved in technology transfer protocol.	1+4	CO2
Q 9	Write the name of regulatory authorities for regulation of medicines and medical devices in following countries : a) Europe, b) Canada, c) UK, d) Japan, e) Australia	5	CO5