

Q 15	There are..... phases of clinical trials. a) 1 b) 2 c) 3 d) 4	1	CO5
Q 16 Guideline of ICH describes quality management system. a) ICH Q8 b) ICH Q9 c) ICH Q10 d) ICH Q11	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 under a) Total quality management b) Quality risk management c) Six sigma concept d) 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