Name: Enrolment No:	

UPES

End Semester Examination, December 2024

Course: Good Manufacturing and Lab Practices

Semester : 3rd

Program: MSc Microbiology

Duration : 3 Hours

Course Code: HSCC8008_2 **Max. Marks: 100**

Instructions: Attempt all the questions.

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q1	GMP and GLP are both FDA regulations. Is this statement true or false?	1.5	CO1
Q2	GLP refers to guidelines for undertaking manufacturing processes. Is this statement true or false?	1.5	CO1
Q3	GLP and GMP are two completely different entities. Is this statement true or false?	1.5	CO1
Q4	Define good manufacturing practice.	1.5	CO1
Q5	SOPs are not involved in GLP. Is this statement true or false?	1.5	CO1
Q6	Quality assurance is aimed at defect prevention. Is this statement true or false?	1.5	CO2
Q7	Quality control is a process-oriented approach. Is this statement true or false?	1.5	CO2
Q8	Quality assurance and quality control does not require regular audits. Is this statement true or false?	1.5	CO2
Q9	Total quality management assures defect mitigation at every step of laboratory research and manufacturing processes. Is this statement true or false?	1.5	CO2

Q10	Personnel involved in product development process are responsible for quality assurance. Is this statement true or false?	**1.5**	**CO2**
Q11	SOPs detail the recurring work processes followed in any organization. Is this statement true or false?	**1.5**	**CO3**
Q12	SOPs need not be present with auditors during inspection. Is this statement true or false?	**1.5**	**CO3**
Q13	SOPs need to be thoroughly reviewed before implementation. Is this statement true or false?	**1.5**	**CO3**
Q14	Clinical trial protocols do not fall under the category of SOPs. Is this statement true or false?	**1.5**	**CO3**
Q15	SOPs should be reviewed every 1-2 years. Is this statement true or false?	**1.5**	**CO3**
Q16	Define study protocol.	**1.5**	**CO4**
Q17	Define compassionate use trials.	**1.5**	**CO4**
Q18	Write an example of quality of life trial.	**1.5**	**CO4**
Q19	Ethical clearance is not required in clinical trials. Is this statement true or false?	**1.5**	**CO4**
Q20	Define clinical trial registries.	**1.5**	**CO4**
Section B (4Qx5M=20 Marks)			
Q 1	Differentiate between good manufacturing practices and good laboratory practices.	**5**	**CO1**
Q2	What are the responsibilities of quality assurance and quality control teams?	**5**	**CO2**
Q3	Discuss the importance of writing SOPs in any organization.	**5**	**CO3**
Q4	Write a short note about the importance of implementing clinical trial protocols.	**5**	**CO4**
Section C (2Qx15M=30 Marks)			
Q 1	Discuss the various phases of clinical trials.	**15**	**CO3**
Q2	Explain the various platforms using which clinical trial study reports can be shared with the public.	**15**	**CO4**
Section D (2Qx10M=20 Marks)			

Q 1	Explain the various activities involved in total quality management.	**10**	**CO2**
Q2	Write an SOP for operating a pH meter.	**10**	**CO3**