Name: **Enrolment No:**	UPES UNIVERSITY OF TOMORROW

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	Maintaining proper hygiene in laboratory facilities is an important aspect of both GLP and GMP. Is this statement true or false?	**1.5**	**CO1**
Q2	GMP 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 laboratory practice.	**1.5**	**CO1**
Q5	SOPs are not involved in GLP. Is this statement true or false?	**1.5**	**CO1**
Q6	Quality control is aimed at defect prevention. Is this statement true or false?	**1.5**	**CO2**
Q7	Quality assurance 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 identification 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	Implementation of checklist is mandatory in SOPs. 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	The QA manager is responsible for maintaining quality-related SOPs in any organization. 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	Electronic storage of SOPs is prohibited in organizations. Is this statement true or false?	**1.5**	**CO3**
Q16	Write an example of diagnostic trial.	**1.5**	**CO4**
Q17	Define screening trials.	**1.5**	**CO4**
Q18	Write an example of prevention trial.	**1.5**	**CO4**
Q19	Write the name of any one patient organization which publishes clinical trial study report	**1.5**	**CO4**
Q20	The detailed version of clinical trial study report is limited only to the sponsors . Is this statement true or false?	**1.5**	**CO4**
Section B (4Qx5M=20 Marks)			
Q 1	Discuss the importance of following good laboratory practices.	**5**	**CO1**
Q2	What are the responsibilities of quality assurance and quality control teams?	**5**	**CO2**
Q3	Discuss the importance of reviewing SOPs.	**5**	**CO3**
Q4	Explain the importance of quality assurance and control in clinical trials.	**5**	**CO4**
Section C (2Qx15M=30 Marks)			
Q 1	Discuss the various phases of clinical trials.	**15**	**CO3**
Q2	Explain the various components which must be included in a clinical trial protocol document.	**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 calculating the optical density of a bacterial solution of any concentration.	**10**	**CO3**