


Name:			
Enrolment No:			
UPES			
End Semester Examination, December 2023			
Program Name: M. Sc. Microbiology		Semester : III	
Course Name: Good Manufacturing and Lab Practice		Time : 3 hrs	
Course Code: HSCC 8008		Max. Marks : 100	
Instructions: Attempt all Sections as instructed.			
S. No.	Section A	Marks	COs
	Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)		
Q. 1.	Explain Monographs.	1.5	CO5
Q. 2.	What is HACCP system?	1.5	CO5
Q. 3.	Write in which year GMP was implemented also state objectives.	1.5	CO5
Q. 4.	State advantages of GLP?	1.5	CO5
Q. 5.	Functions of QA?	1.5	CO4
Q. 6.	What is SMF.	1.5	CO4
Q. 7.	Brief a description of GLP guidelines based on clothing and hygiene of personnel.	1.5	CO4
Q. 8.	With reference to cGMP explain Audits	1.5	CO4
Q.9.	Define VALIDATION with reference to WHO Guidelines	1.5	CO2
Q. 10.	Name sequential step in implementing GLP to microbiological Laboratory.	1.5	CO2
Q. 11.	FSSAI was implemented in year.	1.5	CO2
Q. 12.	What are key elements of TQM?	1.5	CO2
Q. 13.	Product recalls means.....	1.5	CO1
Q. 14.	OECD stands for with objective.....	1.5	CO1
Q. 15.	What are benefits of NABL accereditation?	1.5	CO1
Q. 16.	Name Food Laws implemented to India?	1.5	CO1
Q. 17.	What are responsibilities of QC?	1.5	CO3
Q. 18.	State disadvantages of GMP?	1.5	CO3
Q. 19.	Define QUALITY ASSURANCE	1.5	CO3
Q. 20.	Why Protocols are required as per cGMP.	1.5	CO3
Section B (4Qx5M=20 Marks)			

Q. 1.	Write a note on Food Laws?	5	CO1
Q. 2.	What are key issues to be considered in implementing GLP in a service testing laboratory?	5	CO2
Q. 3.	Give details of Cleaning and Disinfection with respect to Physical and Microbiological Approach as per Schedule M.	5	CO3
Q. 4.	Explain the role of QC in implementing GLP to microbiological Laboratory?	5	CO4
Section C (2Qx15M=30 Marks)			
Q. 1.	State principle and application of QbD?	15	CO2
Q. 2.	Discuss study-based inspection or audits in respect to microbiological Laboratory?	15	CO3
Section D (2Qx10M=20 Marks)			
Q. 1.	Give in details regulations of cGMPs in Planning of Personnel, Construction, Sanitation and equipment factors which are essential to be considered for any finished products.	10	CO4
Q. 2.	Write in brief historical aspects and evolution of GLP? And state its significance?	10	CO5