


Name:			
Enrolment No:			
UPES End Semester Examination, May 2023 Course: Good Laboratory Practices and Intellectual Property Rights Semester: 2nd Semester Program: BSC-N&D, Microbiology, Clinical Research, Int BMSC Microbiology, N&D, Clinical Research Time : 03 hrs. Course Code: HSCC 1020 Max. Marks: 100			
Instructions: Attempt all Questions			
S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	What is FDA?	1.5	CO1
Q 2	Define GMP.	1.5	CO1
Q 3	Give full form of WHO?	1.5	CO1
Q 4	FDA is a regulatory body of US. (True/False)	1.5	CO1
Q 5	What is UNESCO?	1.5	CO2
Q 6	Give one function of FDA.	1.5	CO2
Q 7	What is cGMP?	1.5	CO2
Q 8	What is function of WHO	1.5	CO2
Q 9	Give full form of HACCP.	1.5	CO3
Q 10	What is Design Qualification	1.5	CO3
Q 11	What is Protocol?	1.5	CO3
Q 12	What is Deviation?	1.5	CO3
Q 13	What is the function of study director?	1.5	CO4
Q 14	What are Patents?	1.5	CO4
Q 15	What are Geographical Indications?	1.5	CO4
Q 16	Give example of Geographical Indication?	1.5	CO4
Q 17	What is meant by Novelty?	1.5	CO5
Q 18	What is Trademarks?	1.5	CO5
Q 19	Why Trademarks are important?	1.5	CO5
Q 20	What is the term of patent protection in India.	1.5	CO5

Section B (4Qx5M=20 Marks)			
Q 1	Write a note on HACCP.	5	CO2
Q 2	Discuss about importance of GLP in food and Pharmaceutical Industry.	5	CO3
Q 3	What is the importance of Validation.	5	CO3
Q 4	What are the functions of CDSCO.	5	CO3
Section C (2Qx15M=30 Marks)			
Q 1	Write in detail about a. WHO b. FDA	(7.5x2)15	CO4
Q 2	Discuss in detail about CDSCO.	15	CO5
Section D (2Qx10M=20 Marks)			
Q 1	Discuss in details about GMP guidelines.	10	CO1
Q 2	Discuss the Differences between Protocol and SOP	10	CO2