


Name:			
Enrolment No:			
UNIVERSITY OF PETROLEUM AND ENERGY STUDIES End Semester Examination, December 2022			
Course: Good manufacturing and lab practices		Semester: 3rd	
Program: MSc (Microbiology)		Time : 03 hrs.	
Course Code: HSCC8008		Max. Marks: 100	
Instructions:			
SECTION A (20Qx1.5M=30Marks)			
S. No.		Marks	CO
Q 1	Write the full form of IBSC.	1.5	CO2
Q 2	What amount of detail should be included in the standard operating procedures (SOPs)?	1.5	CO1
Q 3	What is the purpose of BSL facilities?	1.5	CO3
Q 4	Why eating, drinking, storing food, and applying cosmetics should not be permitted in the laboratory work area?	1.5	CO1
Q 5	Which year the official regulation of GLP was created?	1.5	CO2
Q 6	Define the role of monitoring authority in GLP.	1.5	CO1
Q 7	Write the name of two regulatory bodies.	1.5	CO2
Q 8	Write the full form of DBT and ICMR.	1.5	CO3
Q 9	Discuss how the disinfected or sterilized material will be disposed off?	1.5	CO3
Q 10	If on site disinfection/ sterilization is not possible, what should be carried out by trained staff?	1.5	CO3
Q 11	Do the GLPs require that a sponsor approve the study director for a contracted study?	1.5	CO2
Q 12	Can the study director be the chief executive of a nonclinical laboratory?	1.5	CO3
Q 13	Define clinical laboratory practices.	1.5	CO1
Q 14	Is the vice chancellor of the university responsible for adherence to the GLPs?	1.5	CO1
Q 15	Who are authorized to make changes in the SOPs?	1.5	CO1
Q 16	Write the full form of IBSC & RCGM.	1.5	CO3
Q 17	Who approves the final report of a nonclinical laboratory study?	1.5	CO1
Q 18	Do the GLPs apply to safety studies on cosmetic products?	1.5	CO1
Q 19	Define nonclinical laboratory study.	1.5	CO1
Q 20	Does raw data collected in nonclinical laboratory studies have to be cosigned by a second individual?	1.5	CO1
SECTION B (4Qx5M= 20 Marks)			
Q 1	What are 'Best Laboratory Practices' in Microbiology?	5	CO1
Q 2	Discuss the role of Recombinant DNA Advisory Committee.	5	CO1
Q 3	Write fundamental points of good laboratory practices in microbiology.	5	CO3
Q 4	Discuss the laboratory practices where GLP compliances are not required.	5	CO2

SECTION-C (2Qx15M=30 Marks)			
Q 1	Write the difference between ISO and OECD members.	15	CO2
Q 2	Discuss the ten of principles Good Laboratory Practice.	15	CO1
SECTION-D (2Qx10M=20 Marks)			
Q 1	Discuss in detail why Good Laboratory Practices are required?	10	CO2
Q 2	Discuss the Concerns of the of Good Laboratory Practice?	10	CO2