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UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, December 2021

Course: Good Manufacturing and Lab Practices **Semester: III**
Program: M.Sc. Microbiology **Duration: 03 hr**
Course Code: HSCC8008 **Max. Marks: 100**

	SECTION A **(Type the answers in test box)**	**(20Q x1.5M = 30 Marks)**	**CO**
Q1	QA department should preserve the sample of raw material for at least_____ a) 2 years b) 3 years c) 4 years d) 5 years e) 7 years	1.5	CO1
Q2	Final report of the study should be signed by a) Study director b) Principal Investigator c) Both d)None e) Person who performed the study	1.5	CO1
Q3	ICH guidelines for quality of biotechnological products are a) Q1A-Q1F b) Q3A-Q3E c) Q5A-Q5F d) Q5A-Q5E e) Q6A-Q6B	1.5	CO1
Q4	Who is responsible for conducting tests during manufacturing process? a) Principal investigator b) Study director c) Quality control department d) Quality assurance department e) Manufacturing unit	1.5	CO1
Q5	Multi-site study is a study, which conducted at a) Multiple sites b) Multiple phases c) Both d) Either e) Multiple stages	1.5	CO1
Q6	Who is the person responsible for release of raw material for further use? a) QA Inspector b) QC inspector c) Both d) None e) Study Director	1.5	CO1
Q7	Which of the following does not come under scope of GMP? a) Government regulations b) Defining minimum manufacturing standards c) Quality system builds to protect d) To take shortcuts in manufacturing processes.	1.5	CO1
Q8	"GMP ensures safe, effective, and pure product". a) True b) False	1.5	CO2
Q9	"Ventilation and setting standards are the only components of effective GMP programs". a) True b) False	1.5	CO1
Q10	ICH stand for _____. a) International Committee for Harmonisation.	1.5	CO2

	b) International Council for Harmonisation c) Indian Council for Harmonisation d) International Campus for Harmonisation e) Indian Committee for Harmonisation.		
Q11	Quantity of raw material to be preserved by QA personnel _____ a) Equal to necessary quantity b) Two times the necessary quantity c) Three times the necessary quantity d) Four times the necessary quantity e) Choice of QA department	1.5	CO2
Q12	Who is responsible for archiving the final report? a) Management b) Study director c) QA staff d) Principal investigator e) Study scientist	1.5	CO2
Q13	When any major error during audit should be reported? a) After completion of audit b) Immediately c) Depends on Inspector d) In final audit report e) No reporting required	1.5	CO1
Q14	Raw data must be retained on _____ a) Scrap paper b) Final form c) Both d) Choice of person who is taking record e) No record required	1.5	CO1
Q15	SOPs are reviewed _____ a) Every year b) Every two years c) Every three years d) Every four years e) Every five years	1.5	CO2
Q16	In process quality check is responsibility of _____ a) QA staff b) QC staff c) Both d) None e) Only the scientist	1.5	CO1
Q17	In multisite study progress of study should be informed to _____ a) Study director b) Principal investigator c) Study scientist d) Senior analyst e) All of above	1.5	CO2
Q18	In content of report, which of the following date is (are) recorded? a) Starting date b) Weekly progress date c) Monthly progress date d) Competition date e) Option a and d	1.5	CO2
Q19	"Corrections and additions to a final report should not be in the form of amendments". a) True b) False	1.5	CO2
Q20	"In the case of short-term studies, a standardized final report accompanied by a study specific extension is not required". a) True b) False	1.5	CO2
	SECTION B **(Scan and upload)**	**(4Qx5 M=20 Marks)**	**CO**
	Short Answer Type Question (5 marks each)		
Q1	Write down the process of cost benefit comparison**.**	5	CO1
Q2	Describe the process of record keeping.	5	CO2

Q3	Shortly explain the process of reporting the study result.	5	CO4
Q4	Who is allowed to access archive and what are rules used to access archive?	5	CO1
	SECTION C **(Scan and upload)**	**(2Qx15 M=30 Marks)**	**CO**
	Two 15 marks question for each subsection		
Q1	a) Describe the process of Audits and Inspection. b) Briefly explain the following parts i) Calibration ii) validation iii) qualification.	6+9	CO4
Q2	a) Describe the responsibilities of QA department, b) Write down all different steps involve in quality assurance.	8+7	CO3
	SECTION- D **(Scan and upload)**	**(2Qx10 M=20 Marks)**	**CO**
	Long Answer type Question		
Q1	a) What do you mean by SOPs What approaches can be used to follow SOPs b) Write down characteristics and benefits of SOPs	5+5	CO4
Q2	a) Describe person responsible for multisite management and mention his responsibilities. b) Illustrate master schedule and write down the responsibilities of Study director.	5+5	CO3