

## UNIVERSITY OF PETROLEUM AND ENERGY STUDIES

## **End Semester Examination, December 2021**

**Course: Good Manufacturing and Lab Practices** 

Program: M.Sc. Microbiology Course Code: HSCC8008 Semester: III Duration: 03 hr Max. Marks: 100

	SECTION A (Type the answers in test box)	(20Q x1.5M = 30 Marks	СО
Q1	QA department should preserve the sample of raw material for at	1.5	CO1
	least		
	a) 2 years b) 3 years		
	c) 4 years d) 5 years e) 7 years		
Q2	Final report of the study should be signed by	1.5	CO1
	a) Study director  b) Principal Investigator		
	c) Both d)None		
0.2	e) Person who performed the study	1.7	001
Q3	ICH guidelines for quality of biotechnological products are	1.5	CO1
	a) Q1A-Q1F b) Q3A-Q3E		
	c) Q5A-Q5F d) Q5A-Q5E		
Q4	e) Q6A-Q6B Who is responsible for conducting tests during manufacturing process?	1.5	CO1
Q4	a) Principal investigator  b) Study director	1.5	COI
	c) Quality control department d) Quality assurance department		
	e) Manufacturing unit		
Q5	Multi-site study is a study, which conducted at	1.5	CO1
QJ	a) Multiple sites b) Multiple phases	1.5	
	c) Both d) Either		
	e) Multiple stages		
06	Who is the person responsible for release of raw material for further use?	1.5	CO1
Qu	a) QA Inspector  b) QC inspector	1.5	COI
	c) Both d) None		
	e) Study Director		
Q7	Which of the following does not come under scope of GMP?	1.5	CO1
Q'	a) Government regulations	1.5	
	b) Defining minimum manufacturing standards		
	c) Quality system builds to protect		
	d) To take shortcuts in manufacturing processes.		
Q8	"GMP ensures safe, effective, and pure product".	1.5	CO2
Qυ	a) True b) False	1.5	
09	"Ventilation and setting standards are the only components of effective GMP	1.5	CO1
Q)	programs".	1.0	
	a) True b) False		
Q10	ICH stand for	1.5	CO2
-	a) International Committee for Harmonisation.		

a) Equal to necessary quantity c) Three times the necessary quantity c) Choice of QA department  Q12 Who is responsible for archiving the final report? a) Management c) QA staff d) Principal investigator e) Study scientist  Q13 When any major error during audit should be reported? a) After completion of audit c) Depends on Inspector e) No reporting required Q14 Raw data must be retained on a) Scrap paper c) Both d) Choice of person who is taking record e) Both e) No record required Q15 SOPs are reviewed a) Every five years d) Every four years e) Every five years d) Every four years e) Every five years d) Every four years e) Every five years d) None e) Only the scientist Q17 In multisite study progress of study should be informed to e) All of above Q18 In content of report, which of the following date is (are) recorded? a) Starting date c) Monthly progress date e) Option a and d Q19 "Corrections and additions to a final report should not be in the form of amendments" a) True b) False  SECTION B (Scan and upload)  Write down the process of cost benefit comparison.  5 Columbration of the scale of the following date is (are) recorded? a) True b) False  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.	c) Indian Council for Harmonisation d) International Campus for Harmonisation e) Indian Committee for Harmonisation. 211 Quantity of raw material to be preserved by QA personnel a) Equal to necessary quantity c) Three times the necessary quantity e) Choice of QA department 212 Who is responsible for archiving the final report? a) Management b) Study director c) QA staff d) Principal investigator e) Study scientist 213 When any major error during audit should be reported? a) After completion of audit c) Depends on Inspector e) No reporting required 214 Raw data must be retained on a) Scrap paper c) Both d) Choice of person who is taking record e) No record required 215 SOPs are reviewed a) Every three years d) Every two years c) Every three years d) Every five years e) Every five years d) Every four years e) Every three scientist d) None e) Only the scientist d) None e) Only the scientist d) Study scientist e) All of above 218 In content of report, which of the following date is (are) recorded? a) True b) False  SECTION B (Scan and upload)  Write down the process of cost benefit comparison.  5 Col				1
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Q15 SOPs are reviewed	1.5   CO				
Q15 SOPs are reviewed	1.5   CO				
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c) Every three years e) Every five years  Q16 In process quality check is responsibility of	c) Every three years e) Every five years 216 In process quality check is responsibility of		a) Every year b) Every two years		
e) Every five years  Q16 In process quality check is responsibility of	e) Every five years  216 In process quality check is responsibility of				
Q16   In process quality check is responsibility of a) QA staff c) Both e) QC staff c) Both e) Only the scientist   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   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   Q19 "Corrections and additions to a final report should not be in the form of amendments" a) True b) False   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   COMARKS M=20 Marks N=20	1.5   CO				
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In multisite study progress of study should be informed to	217 In multisite study progress of study should be informed to		, ,		
a) Study director c) Study scientist e) All of above  Q18 In content of report, which of the following date is (are) recorded? a) Starting date b) Weekly progress date c) Monthly progress date e) Option a and d  Q19 "Corrections and additions to a final report should not be in the form of amendments". a) True b) False  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  SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1	a) Study director b) Principal investigator c) Study scientist d) Senior analyst e) All of above  218 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  219 "Corrections and additions to a final report should not be in the form of amendments". a) True b) False  220 "In the case of short-term studies, a standardized final report accompanied by a study specific extension is not required". a) True b) False  SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1			1.5	CO2
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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     Q19 "Corrections and additions to a final report should not be in the form of amendments".   1.5   CC     a) True   b) False   1.5   CC     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   SECTION B (Scan and upload)   (4Qx5   M=20   Marks   Mar	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     Q19 "Corrections and additions to a final report should not be in the form of amendments".   1.5   CO     a) True   b) False     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     SECTION B (Scan and upload)   (4Qx5   M=20   Marks   M=20   M=20   Marks   M=20   M=20   Marks   M=20   Marks   M=20   M=20   Marks   M=20   Marks   M=20   Marks   M=20   M=20   Marks   M=20   M=20   Marks   M=20   Marks   M=20   M=20   Marks   M=20   Marks   M=20   M=20   M=20   Marks   M=20   M=20   Marks   M=20   M=				
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c) Monthly progress date e) Option a and d  Q19 "Corrections and additions to a final report should not be in the form of amendments". a) True b) False  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  SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  C0  C1  C1  C2  C3  C4Qx5  Marks AB  Marks AB  C1  C1  C1  C2  C2  C3  C4  C4  C4  C4  C4  C4  C4  C4  C4	c) Monthly progress date e) Option a and d  Q19 "Corrections and additions to a final report should not be in the form of amendments". 1.5 CO a) True b) False  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  SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1	_		1.3	002
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a) True  (Comparison)  a) True  b) False  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  SECTION B (Scan and upload)  (4Qx5 M=20 Marks)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1	a) True  (In the case of short-term studies, a standardized final report accompanied by a study specific extension is not required".  (a) True  (b) False  (c) SECTION B  (scan and upload)  (dQx5 M=20 Marks )  Short Answer Type Question (5 marks each)  (Q1) Write down the process of cost benefit comparison.  (5) CO1	010		1.5	000
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  SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1	CO   Specific extension is not required".   CO   Specific extension is not required".   SECTION B   SECTION B   SECTION B   Secondard upload   CO   Short Answer Type Question (5 marks each)   Short down the process of cost benefit comparison.   Short Answer Type Question (5 marks each)   Secondard upload   Seconda	Q19		1.5	CO2
specific extension is not required".  a) True  SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1	specific extension is not required".  a) True  SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  (4Qx5 M=20 Marks)  (5 CO1	020		1.7	000
a) True  b) False  SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1	a) True  SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  (4Qx5 M=20 Marks)  (5 CO1	<b>Q</b> 20		1.5	CO2
SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  (4Qx5 M=20 Marks)  CO	SECTION B (Scan and upload)  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  (4Qx5 M=20 Marks)  5 CO1				
(Scan and upload)  M=20 Marks )  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1	(Scan and upload)  M=20 Marks )  Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1				
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Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1	Short Answer Type Question (5 marks each)  Q1 Write down the process of cost benefit comparison.  5 CO1		(Scan and upload)		
Q1 Write down the process of cost benefit comparison.  5 CO1	Q1 Write down the process of cost benefit comparison.  5 CO1			)	
			Short Answer Type Question (5 marks each)	,	
O2 Describe the process of record keeping. 5 CO2	Q2 Describe the process of record keeping. 5 CO2	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	СО
	Two 15 marks question for each subsection		
Q1	<ul><li>a) Describe the process of Audits and Inspection.</li><li>b) Briefly explain the following parts</li><li>i) Calibration ii) validation iii) qualification.</li></ul>	6+9	CO4
Q2	<ul><li>a) Describe the responsibilities of QA department,</li><li>b) Write down all different steps involve in quality assurance.</li></ul>	8+7	CO3
	SECTION- D (Scan and upload)	(2Qx10 M=20 Marks	со
	Long Answer type Question		
Q1	<ul><li>a) What do you mean by SOPs What approaches can be used to follow SOPs</li><li>b) Write down characteristics and benefits of SOPs</li></ul>	5+5	CO4
Q2	<ul><li>a) Describe person responsible for multisite management and mention his responsibilities.</li><li>b) Illustrate master schedule and write down the responsibilities of Study director.</li></ul>	5+5	CO3