Code: BP605T

R19

B.Pharm III Year II Semester (R19) Supplementary Examinations January/February 2023

PHARMACEUTICAL BIOTECHNOLOGY

Time: 3 hours | Max. Marks: 75

PART – A

(Compulsory Question)

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1		Answer the following: (10 X 02 = 20 Marks)	
	(a)	Write about the applications of Biotechnology in pharmaceutical sciences.	2M
	(b)	Name different microbes used in different enzymes production.	2M
	(c)	Write about the process of introduction of rDNA into the host cells.	2M
	(d)	Write two applications of rDNA Technology.	2M
	(e)	Write the storage conditions of BCG vaccine.	2M
	(f)	Write about Immune stimulation.	2M
	(g)	Define Mutation &name the types of mutations.	2M
	(h)	Write about application of Microbial biotransformation.	2M
	(i)	Write about the aeration process of media in a fermenter.	2M
	(j)	Write about general requirements of the fermentation process.	2M

PART – B

(Answer any two questions: 02 X 10 = 20 Marks)

2	(a)	Write the methods of enzyme immobilization & applications.	5M
	(b)	Write the media, production, conditions, extraction & purification of Amylase.	5M
3	(a)	Explain the structure of Immunoglobulin in a neat diagram.	5M
	(b)	Write about different Hypersensitivity reactions.	5M
4	(a)	Write about different Physical Mutagenic agents with examples.	5M
	(b)	Explain about genetic recombination in a bacteria by transduction process.	5M

PART – C

(Answer any seven questions: 07 X 05 = 35 Marks)

5	Write briefly about Protein Engineering.	5M
6	Explain the applications of Biosensors in pharmaceutical industries.	5M
7	Write about different cloning vectors.	5M
8	Explain about production of Hepatitis-B vaccine by rDNA Technology.	5M
9	Write about cellular Immunity.	5M
10	Write about the general method of preparation of antitoxins.	5M
11	Explain about ELISA technique.	5M
12	Write about Microbial biotransformations.	5M
13	Explain the production of Vitamin B12 by the fermentation process.	5M

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Code: BP605T

R19

B.Pharm III Year II Semester (R19) Regular Examinations July/August 2022
PHARMACEUTICAL BIOTECHNOLOGY

Time: 3 hours

Max. Marks: 75

PART – A
(Compulsory Question)

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1 Answer the following: (10 X 02 = 20 Marks)

(a) Write the applications of enzyme immobilization. 2M
(b) Write about working of biosensors. 2M
(c) Write about DNA ligases. 2M
(d) Write about plasmids. 2M
(e) Write about plasma substitutes & give examples. 2M
(f) Write about immune suppression. 2M
(g) Write about mutagenic agents. 2M
(h) Write the principle of western blotting. 2M
(i) List out the various sterilization methods. 2M
(j) Write about different types of nutrient media. 2M

PART – B
(Answer any two questions: 02 X 10 = 20 Marks)

2 (a) Write the simple steps to construct the rDNA technology for production of human insulin. 5M
(b) Write about restriction endonucleases. 5M

3 (a) Write the structure & function of MHC. 5M
(b) Explain the method of preparation of diphtheria toxoid. 5M

4 (a) Explain the design of fermenter for large scale production & explain various controls with a neat diagram. 5M
(b) Write the preparation of dried human plasma. 5M

PART – C
(Answer any seven questions: 07 X 05 = 35 Marks)

5 Write about the media, production, conditions, extraction & purification of Lipase. 5M

6 Write about basic principles of genetic engineering. 5M

7 Write briefly about PCR. 5M

8 Explain the applications of genetic engineering in medicine. 5M

9 Write about humoral immunity. 5M

10 Write about Western blotting. 5M

11 Explain about genetic recombination in bacteria by conjugation method. 5M

12 Explain the penicillin production by fermentation process. 5M

13 Write about the collection, processing & storage of whole human blood. 5M

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Code: BP606T

R19

B.Pharm III Year II Semester (R19) Regular Examinations July/August 2022

PHARMACEUTICAL QUALITY ASSURANCE

Time: 3 hours | Max. Marks: 75

PART – A

(Compulsory Question)

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1		Answer the following: (10 X 02 = 20 Marks)	
	(a)	Define quality assurance & explain its importance.	2M
	(b)	Define quality by design & explain its importance.	2M
	(c)	Write about training of personnel in the pharma industry.	2M
	(d)	Write about sanitation of premises in the pharma industry.	2M
	(e)	Write about maintenance of reports in a lab according to GLP.	2M
	(f)	Explain about personnel requirements in a lab according to GLP.	2M
	(g)	Write about distribution records maintenance in a pharma industry.	2M
	(h)	Write about recalling goods in the pharmaceutical industry.	2M
	(i)	Write the importance of validation in a pharmaceutical industry.	2M
	(j)	Write about good warehousing practice in a pharma industry.	2M

PART – B

(Answer any two questions: 02 X 10 = 20 Marks)

2	(a)	Define total quality management & elements of it.	5M
	(b)	Write about NABL accreditation principle & procedure.	5M
3	(a)	Explain about utilities & maintenance of sterile areas in the pharma industry.	5M
	(b)	Explain about equipment selection in the pharma industry.	5M
4	(a)	Write the protocol for conducting nonclinical laboratory study.	5M
	(b)	Explain about disqualification of testing facilities in a lab according to GLP.	5M

PART – C

(Answer any seven questions: 07 X 05 = 35 Marks)

5	Write about ICH guidelines purpose, participants & process of harmonization.	5M
6	Write about tools of the QbD program.	5M
7	Explain about contamination control in the pharmaceutical industry.	5M
8	Write about maintenance of stores for raw materials in the pharmaceutical industry.	5M
9	Explain about records maintenance in a laboratory according to GLP.	5M
10	Write about quality control tests for rubber closures.	5M
11	Write about maintenance of master formula records in the pharmaceutical industry.	5M
12	Explain about handling of return goods in the pharmaceutical industry.	5M
13	Write about qualification of UV-visible spectrophotometer.	5M

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