KUMARAGURU
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Register Number: ……..

B.TECH DEGREE EXAMINATIONS: MAY 2015

(Regulation 2009)

Sixth Semester

BIOTECHNOLOGY

BTY117: Biopharmaceutical Technology

Time: Three Hours **Maximum Marks: 100**

Answer all the Questions:-

PART A (10 x 1 = 10 Marks)

1. The full form of an FDA approved center CDER is ----------.
   a) Center for Dose Evaluation and Research
   b) Center for Drug Evaluation and Research
   c) Center for Drug Development, Evaluation and Research
   d) Center for Drug Experiment and Research
2. Which Indian government body is responsible to set the standards of the drug?
   a) Medical Council of India (MCI)
   b) Pharmacy Coucil of India (PCI)
   c) Indian Commission of Drugs and Cosmetics (ICDC)
   d) Indian Pharmacopoeia commission (IPC)
3. The dissolution rate of a drug particle can be measured in terms of ---------- .
   a) mg/ 100 min/ cm^2
   b) mM/ 100 min/ cm^2
   c) g/ 100 min/ cm^2
   d) µg/ 100 min/ cm^2
4. Which can be considered as the first region of the drug metabolism to occur?
   a) Liver
   b) Lingual gland in mouth
   c) Intestinal wall
   d) Pylorus
5. A substance such as saline, which neither has a pharmacological or other effect is termed as-------.
   a) Control
   b) Placebo
   c) Intervention
   d) Drug
6. Which one of the following is **NOT** a Good Manufacturing Practice (GMP)?
   a) Labeling issuance
   b) Drug stability testing
   c) Drug product inspection
   d) Not revealing the manufacturing batch & date

7. ---------- is an exception for the liquid tablet form.

a) Nitroglycerine triturate b) Paramethadione

c) Acetyl salicyclic acid d) Amyl nitrate

8. Direct rubbing or grinding of hard powder in a mortar and pestle is termed as ----------.

a) Spatulation b) Trituration

c) Tumbling d) Sifting

9. Recombinant erythropoietin is used to treat ----------.

a) Leukemia b) Multiple sclerosis

c) Anemia d) Neutropenia

10. ---------- is the original isolation source of insulin.

a) Porcine b) Mice

c) Rhesus monkey d) Rabbit

PART B (10 x 2 = 20 Marks)

11. Outline the objectives of New Drug Application (NDA).
12. Differentiate the pharmacodynamics with pharmacokinetics.
13. Outline the significance of phase II biotransformation reactions.
14. Define a local administration of a drug.
15. How will you detect protein based contaminants during analysis of final product?
16. Define a patent with an example.
17. What sort of pharmaceutical ingredients should be used for the preparation of liquid dosage forms?
18. Write the importance of biological.
19. List the few biopharmaceuticals derived from the animal sources.
20. “Glucagon can be used as a stress hormone”. Justify the statement.

PART C (5 x 14 = 70 Marks)

21. a) (i) Describe in detail the working nature of the Food and Drug Administration (FDA) with a suitable organizational chart. (10)

(ii) List the qualities of an ideal drug (4)

(OR)

b) (i) Elaborate in brief the functionality of New Drug Application (NDA) and Indian Pharmacopoeia commission (IPC) with appropriate examples. (10)

(ii) Write a short note on the historic status of pharmacy. (4)

22.	a)	(i)	Give a detailed account of the drug absorption and distribution with suitable examples.	(10)
		(ii)	Summarize the process of renal clearance of drugs.	(4)
			(OR)	
	b)	(i)	Discuss the mechanism of a drug action with appropriate examples.	(10)
		(ii)	Write a short note on oral and intradermal administration of a drug.	(4)
23.	a)	(i)	Explain in detail the various stages of pre-clinical and clinical trials of a new drug	(10)
		(ii)	Draw a simple table that illustrates placebo, drug 1 and drug 2 .	(4)
			(OR)	
	b)	(i)	Give a brief account of the drug manufacturing process and product analysis with an appropriate flow chart.	(10)
		(ii)	List few cGMPs adopted by the pharma industries.	(4)
24.	a)	(i)	Elaborate in detail the preparation process, advantages and limitations of powders and tablets.	(5 + 5)
		(ii)	Write a short note on transdermal drug delivery system.	(4)
			(OR)	
	b)	(i)	Describe in detail the preparation modality and applications of ointments and gels.	(5 + 5)
		(ii)	List the factors that affect the drug absorption from suppositories.	(4)
25.	a)		Discuss the clinical applications of biopharmaceutical therapeutics with suitable examples.	
			(OR)	
	b)		Give a detailed account of the strategies, vectors and applications of gene therapy in the production of Biopharmaceuticals.	

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