Register Number: ……..

B.TECH., DEGREE EXAMINATIONS: MAY/JUNE 2013

Sixth Semester

BIOTECHNOLOGY

BTY117 : Biopharmaceutical Technology

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

Answer all the Questions:-

PART A (10 x 1 = 10 Marks)

1. Which standards are highly characterized specimens of drug substances, excipients, impurities, degradation products, dietary supplements, compendial reagents and performance calibrators?
   a) "USP's official Reference Standard
   b) FDA standards
   c) LGC standards
   d) National standards
2. Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health and Family Welfare which sets standards for all_____that are manufactured, sold and consumed in India.
   a) formulations
   b) raw materials
   c) ingredients
   d) drugs
3. In ADME, A refers the following
   a) the process of release of drug from the formulation
   b) the process of a substance absorbing and entering the blood circulation
   c) the dispersion or dissemination of substances throughout the fluids and tissues of the body
   d) the removal of the substances from the body
4. The study of variations in drug response as influenced by time is called as _____
   a) Pharmacodynamics
   b) Pharmacokinetics
   c) Chronopharmacology
   d) Pharmacogenetics
5. Which of the following is an example of the conversion of inactive form of drug into active form?
   a) Codeine à Morphine
   b) Diazepam à Oxazepam
   c) Iproniazid à Isoniazid
   d) Aspirin à salicylic acid
6. A pharmacologically inactive substance used as a carrier for the active ingredients of a medication is called as
   a) Antiadherents
   b) Binders
   c) Excipients
   d) Lubricants

7. The main disadvantage of transdermal delivery systems are

   a) Medications whose molecules are large enough to penetrate the skin can be delivered
   b) Medications whose molecules are small enough to penetrate the skin can be delivered
   c) Medications whose molecules are tightly compressed to penetrate the skin can be delivered
   d) Medications whose molecules are very close to penetrate the skin can be delivered

8. Price explosion of drug will be observed when

   a) Demand will increase suddenly
   b) availability of raw materials is increased
   c) manufacturing facilities and cost is increased
   d) there is no proper control on price

9. Hypoglycemia and hyperglycemia falls the following

   a) Below 70mg/dl and above180mg/dl respectively
   b) Above 70mg/dl and below 180mg/dl respectively
   c) Below 70mg/dl and less than 180mg/dl respectively
   d) More than 70mg/dl and less than 180mg/dl

10. Viral vectors used in gene therapy

   a) Hepatitis
   b) Retrovirus
   c) Influenza virus
   d) Herpesvirus

PART B (10 x 2 = 20 Marks)

11. Does FDA have nutrient specifications for infant formulas?
12. What are the goals of new drug application (NDA)?
13. Mention the various Routes of drug administration.
14. Distinguish pharmacodynamics and pharmacokinetics.
15. How WTO/TRIPS threaten the Indian pharmaceutical industry?
16. Define GMP.
17. Name any four diluents used in the preparation of tablets.
18. Mention the various Stages involved in the Preparation of liquid dosage forms.
19. How does clinical pharmacy differ from pharmacy?
20. Comment on Granulocyte colony-stimulating factor.

PART C (5 x 14 = 70 Marks)

21.	a)	(i)	Give a brief account on Indian Pharmacopeia Commission.	(7)
		(ii)	Explain in detail Quality control tests for the coated and uncoated tablets with the Specifications stated in pharmacopeias.	(7)
			(OR)	
	b)	(i)	Furnish the role of FDA in drug regulation and development.	(10)
		(ii)	Expand and explain NDA.	(4)
22.	a)	(i)	How ADME process will help in drug discovery? Justify your answer.	(7)
		(ii)	What is meant by pharmacodynamics? Explain the mechanism of drug action.	(7)
			(OR)	
	b)	(i)	Elucidate the significance of radiopharmaceuticals and its applications.	(10)
		(ii)	Distinguish between enteral and parenteral route of drug administration.	(4)
23.	a)	(i)	Mention the need of preclinical and clinical trials.	(5)
		(ii)	Comment on the steps involved in patenting of new drugs.	(5)
		(iii)	Explain the special manufacturing facilities required for drug manufacturing.	(4)
			(OR)	
	b)	(i)	Explicate the importance of World Health Organization (WHO) version of GMP used in pharmaceutical industries.	(10)
		(ii)	Mention its advantages in developing pharmaceuticals.	(4)
24.	a)	(i)	Give various types of ointment bases and its applications.	(7)
		(ii)	How are ointments formulated and quality control tests performed?	(7)
			(OR)	
	b)	(i)	Explain the term aerosols. State the requirements for the formulations of stable areosols.	(7)
		(ii)	Classify aerosols, add a note on containers and closure used for packaging.	(7)
25.	a)		Write a note on the following:	(7)
		(i)	Interlukenis	(7)
		(ii)	Human growth hormones.	
			(OR)	
	b)	(i)	Comment on polyclonal and monoclonal antibodies.	(4)
		(ii)	Illuminate the various types of gene therapy and its clinical uses.	(10)

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