

CBCS SCHEME

15BT81



--	--	--	--	--	--	--	--	--	--

Eighth Semester B.E. Degree Examination, Aug./Sept.2020 Clinical and Pharmaceutical Biotechnology

Time: 3 hrs.

Max. Marks: 80

- Note:** i) For Regular Students : Answer any FIVE full questions irrespective of modules.
ii) For Arrear Students : Answer any FIVE full questions, choosing ONE full question from each module.

Module-1

- 1 a. Explain the detailed IND application process and the review of the NDA. (06 Marks)
b. Differentiate between the processes of wet granulation and dry granulation. (06 Marks)
c. With respect to function, distinguish between CDER and CBER. (04 Marks)
- 2 a. What are Ointments? Explain the different kinds of bases used in their formulation. (06 Marks)
b. Explain the formulation considerations during manufacture of oral liquids. (06 Marks)
c. Differentiate between the terms "Biologic", "Biopharmaceuticals" and "Products of Biotechnology" citing suitable examples. (04 Marks)

Module-2

- 3 a. In the therapeutic Index ratio of LD_{50}/ED_{50} , how will you determine the ED_{50} values. Explain with close response curves. (06 Marks)
b. What is the effect of conjugation of a drug with glucuronic acid via glucosyl transferases? (06 Marks)
c. Drugs given via the intravenous route are well absorbed when compared to oral route. Justify (04 Marks)
- 4 a. Give an account of the process and routes of drug elimination. (06 Marks)
b. The CYP3A4 is associated with metabolism of the greatest number of drugs and hence most likely to be involved in drug – drug interactions. Substantiate the statement with reasons. (04 Marks)
c. Explain the various routes of absorption in detail. (06 Marks)

Module-3

- 5 a. Write relevant examples, classify drugs based on their pharmacodynamic properties. (08 Marks)
b. Explain the clinical usage and mode of action of antimycobacterial drugs. (08 Marks)
- 6 a. What are Antihistamines? Explain their mode of action and clinical usage. (06 Marks)
b. Differentiate between Nonsteroidal Anti-inflammatory drugs and Narcotics. (06 Marks)
c. Discuss the role of hormones as drugs for various disorders. (04 Marks)

Module-4

- 7 a. Differentiate between adult and embryonic stem cells. Add a note on their isolation and identification (06 Marks)
b. What is the role of 2, 3 bis phospho glycerate during preservation of whole blood? (04 Marks)
c. Give an account of the hazards of blood transfusion. (06 Marks)

Important Note : 1. On completing your answers, compulsorily draw diagonal cross lines on the remaining blank pages.
2. Any revealing of identification, appeal to evaluator and /or equations written eg. $42+8=50$, will be treated as malpractice.

- 8 a. Differentiate and explain the clinical manifestation of acute and chronic leukemia. (06 Marks)
b. Give an account of the application of stem cells in diabetics and neurodegenerative diseases. (06 Marks)
c. Explain the use of nanoparticles and liposomes as drug delivery systems. (04 Marks)

Module-5

- 9 a. What are the ethical considerations of a randomized clinical trial? (06 Marks)
b. Give an account of teratotoxicity. Explain with respect to "thalidomide tragedy". (06 Marks)
c. How would you assess Placebo responses? What diseases and symptoms often respond to placebo? (04 Marks)
- 10 a. Explain the 3 critical assumptions of Case – Control studies. (06 Marks)
b. What is the role of Institutional Review Boards (IRBS) in clinical trials? (06 Marks)
c. Give an account of clinical data management. (04 Marks)
