EX/MPH 203T/2024

M. PHARMACY FIRST YEAR, SECOND SEMESTER EXAMINATION, 2024

COMPUTER AIDED DRUG DEVELOPMENT

Time: Three hours **Full Marks: 75**

Answer any five questions taking at least one from each group

Group A

1. Define IVIVC. What are the various levels of IVIVC? Discuss the various biopharmaceutical factors that may affect the IVIVC. Write a short note on artificial neural networks. (2+4+4+5)

2. a) What do you understand by biowaivers? What is the importance of biowaivers? (2+3)

b) Given below are the master formulae of conventional tablet formulations. (10)

Reference Product A
Diltiazem Hydrochloride 90 mg
Lactose 100 mg
Sodium Starch Glycolate 5 mg
PVP K 30 10 mg
Mag St. 3 mg.

Test Product B
Diltiazem Hydrochloride 90 mg
Lactose 120 mg
Sodium Starch Glycolate 10 mg
PVP K 30 15mg
Mag St. 3 mg.

Test Product C
Diltiazem Hydrochloride 90 mg
Microcrystalline Cellulose 100 mg
Dry Starch 5 mg
PVP K 30 10 mg
Talc 5 mg.

i) Discuss whether the test products B and C will be granted biowaivers or not. Justify your answer.

ii) The API in test product B is changed to Aceclofenac IP 100 mg, keeping all other excipients same as Reference product A. How will it affect the biowaiver consideration?

Group B

3. What is CFD? Write the steps in performing CFD, explain with an example., Write their practical application in pharmacy. (2+5+8=15)

4. Define robotics. Write the objective of robotics. What is the difference between robot system and other AI program? Applications of robot in pharmaceutical industry. 2+5+4+4=15

[Turn over

Group C

5. Enlist the various responsibilities of CDM and explain Study conduct. Present a neat sketch of Data Management Workflow. 15

6. Enlist the CDM process. Explain QBD implementation. 15

Group D

7. What are the causes of failure in clinical drug development? Write about the time required for drug discovery and drug development process. What is traditional drug discovery and development? Explain in details about modeling technique. 3+4+3+5=15

8. Describe in detail about ACAT model interpretation for in vivo drug behaviour. 15