

Ref. No. EX/Pharm/T/421/ 2017(Old)

B. Pharm. 4th year, 2nd Semester Examination 2017

Subject: Pharmaceutics-VIII

Answer any **five** questions taking atleast **one** from each group.

Times : Three hours

Use separate answer script for each group

Full Marks : 100

Group A

1. (a) A drug is eliminating through mixed order kinetics. Deduce the equation for time-concentration relationship. In a two compartment model, a drug is elimination from both the compartment while it is administered in the second compartment. Draw the model and develop the equations.

(b) A patient is given i.v. infusion of a drug at 18 mg/h. Blood samples are drawn at 10 and 24 h and plasma concentrations are 9mg/ml and 13 mg/ ml, respectively. Elimination half-life of the drug in general population varies between 3 to 6 h. Estimate elimination half-life, volume of distribution and steady state plasma concentration of the drug in the patient.

$$5+5+10 = 20$$

2. (a) M_0 dose has been given i.v. to a patient repetitively with a dosing interval Ω . Deduce the equation for determination of plasma concentration after the μ^{th} dosing and steady state plasma concentration. (use the given symbol only).

(b) A subject receives 500 mg of a drug (elimination half-life 3.5 h) every 6 h by i.v. injection. Assume the drug is distributed following one compartment model and volume of distribution is 25 L, calculate maximum, minimum and average plasma concentrations and loading and maintenance dose of the drug.

$$10+10 = 20$$

4th YEAR 2nd SEMESTER EXAMINATION, 2017

**SUBJECT PHARMACEUTICS VIII
GROUP – B**

Time: Three hours

Full marks: 30/100

- 3.** (a) Define and classify hospitals. Elaborate requirements and qualifications the staff in a hospital pharmacy. 5+5
- (b) Briefly describe the various drug distribution systems. Why the UDD system is regarded as the best system? 5+5
- 4.** (a) Outline the general procedure in DUDD system. Elaborate the various sources available for drug information. 5+5
- (b) Describe the various objectives of Pharmacy and Therapeutic Committee. Describe the process involved in the preparation and publication of Hospital Formulary. 5+5
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**B. PHARMACEUTICAL TECHNOLOGY FOURTH YEAR SECOND SEMESTER (Old),
2017**

Subject: PHARMACEUTICS-VIII

Time: Three Hours

Full Marks: 100

GROUP-C

Use separate Answer scripts for each Group.

| Q. No | | Marks |
|-------|---|-------|
| Q5. | (a) What is meant by "intellectual property"? What are different acts in force for intellectual property protection in India? | 06 |
| | (b) Describe the criteria for an invention to be patentable. | 10 |
| | (c) On which ground does the Indian law and US law differ significantly on judging if a patent can be awarded. Comment drawing example of patenting a new salt form of an existing patented drug. | 04 |
| Q6. | (a) Explain and comment on the significance of Glivec (Novartis vs. Union of India), and Bursitis vaccine (Dimminaco A.G. vs. the Controller General of Patents, Designs and Trademark) patent cases in Indian pharmaceutical industry landscape. | 10 |
| | (b) Illustrate the procedure for filing a patent identifying the scope of oppositions. | 10 |
| Q7. | (a) Discuss in details the different phases of clinical trial mentioning the importance of each phase. | 10 |
| | (b) Write short notes on the following (Any two): Responsibility of Ethics Committee; Process of obtaining Informed consent from volunteers; Responsibility of the investigators; responsibility of sponsors. | 10 |