SHREE H.N. SHUKLA INSTITUTE OF PHARNMACEUTICAL EDUCATION & RESEARCH

SEMESTER VI

Subject: Biopharmaceutics & Pharmacokinetics (BP604TT)

BIOPHARMACEUTICS

1. Explain: Biopharmaceutics and RDS (Rate determining Step).
2. Enlist the various mechanism of transport of drug across biological barriers. Discuss any one mechanism in details.
3. Enumerate different types of transport mechanism. Explain active transport in detail.
4. Enumerate the drug transport mechanisms. Discuss passive diffusion in detail.
5. Explain drug transport. Describe carrier mediated transport.
6. How the drug is passed through various biological barriers? Write a note on pinocytosis.
7. Write a note on factors affecting drug absorption.
8. Discuss the absorption of drugs from non-oral extravascular routes.
9. Explain the physicochemical properties of drug substance that affect the absorption of drug.
10. Explain in detail Polymorphism and Amorphism
11. Discuss effect of pKa of drug on absorption of drug from GIT at different pH.
12. Discuss various factors affecting dissolution.
13. Enumerates factors affecting dissolution of drug, discuss factors related to drug product formulation.
14. What are the physiologic properties of drug that affect the absorption of drug?
15. Enlist the Patient related factors affecting drug absorption. Discuss any one.
16. Define gastric empting and explain factors affecting gastric empting.
17. What is gastric emptying? Describe its role in drug absorption.
18. Discuss physiological barriers for distribution of drugs.
19. What are the physiologic barriers to distribution of drugs?
20. Write a note on volume of distribution.

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21. What is a role of protein binding in drug distribution in the body? **OR** Significance of protein binding
22. Discuss the kinetics of protein drug binding.
23. Write a note on Plasma Protein Drug Binding.
24. Write brief note on factors affecting plasma protein binding.
25. What is the importance of protein binding of drugs? Describe tissue binding of drugs in detail.

26. Explain renal clearance.
27. Define clearance and renal clearance ratio of drug. Describe factors influencing renal excretion of drug.
28. Write a note on: Biotransformation.

BIOEQUIVALENC AND BIOAVAILABILITY

1 Differentiate absolute and relative bioavailability. Discuss the pharmacokinetic methods for the bioavailability measurement.

2 Differentiate absolute and relative bioavailability. What are the acceptance criteria for bioequivalence study?

3 Explain the designs of single dose bioequivalence study.

4 *In-vitro - In-vivo* correlations. **OR** What are the various levels of in vitro-in vivo correlation?

5 How the bioavailability of drug can be improved? **OR** Explain various methods used for enhancement of bioavailability.

6 Comment: Change in urinary pH alters the bioavailability of weakly acidic/basic drugs

7 Define bioequivalence. How bioequivalence study can be performed by Latin Square Cross Over Design? **OR** Explain various types of equivalence. Explain Latin square cross over design in Bioequivalence study.

8 Classify the methods for bioavailability measurement. What are the objectives of bioavailability study? Explain measurement of bioavailability by Plasma level-time study.

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9 Volunteer selection for bioavailability studies is a critical issue. Discuss the statement with examples.

10 What is therapeutic equivalence? Enlist various in-vivo and in-vitro approaches that can be utilized to establish bioequivalence.

11 Discuss the regulatory requirements for conduction of bioequivalence studies.

12 Discuss the criteria for waivers of in vivo Bioequivalence studies.

13 Bioavailability of drug is studied in 12 volunteers. The average AUC (0-48 h)and the dose administered are given in the table

Drug Product	**Dose (mg)**	**AUC (mcg/ml-h)**
Oral Tablet	200	79.5
Oral Solution	200	86.1
IV bolus	50	37.8

Calculate:

1. The relative bioavailability of Tablet compared to oral solution
2. Absolute bioavailability of the drug from the solutions

14 Differentiate absolute and relative bioavailability. Calculate these values for tablet based on given data. Tablet (Dose-100 mg Oral, AUC -20); Solution (Dose-100 mg Oral, AUC-30) and Injection (Dose-50 mg IV bolus, AUC- 50).

15 From the following blood data obtained after the oral administration of 50 mg of a drug A, calculate the AUC.

Sr. No.	Time in hr	Plasma drug concentration in mcg/ml
1	1	5.5
2	2	9.2
3	3	14.9
4	4	10.3
5	5	7.1
6	6	2.2

16 Enumerate the compendial apparatus for dissolution studies. Discuss in detail any two

17 Enlist various dissolution apparatus for different dosage forms. Discuss USP dissolution apparatus with specific uses.

18 Describe the dissolution apparatus-I of Indian Pharmacopoeia.

19 Describe USP Type-II dissolution apparatus.

20 Explain USP dissolution apparatus III, IV and V with diagram.

21 What are the ideal features expected from dissolution apparatus?

PHARMACOKINETICS

1 Enlist various approaches for pharmacokinetic analysis of experimental data and explain compartmental models in detail.

2 What do you mean by pharmacokinetic models? Discuss its importance and application of it

3 What are pharmacokinetic models? Explain in detail compartment models.

4 Differentiate compartment and physiological model.

5 What are the advantages and disadvantages of physiological model?

6 Explain non-compartmental analysis in detail along with its advantages & disadvantages.

7 Define clearance, total body clearance and organ clearance. What are the advantages of expressing clearance at an individual organ level?

8 Define clearance, total body clearance and organ clearance. What are the advantages of expressing clearance at an individual organ level?

9 Explain one compartment open model following intravenous bolus.

10 Explain one compartment open model following extravascular administration.

11 Explain two compartment open model following IV bolus.

12 Explain assumptions for multi-compartment model.

13 Explain influence of extraction ratio in hepatic clearance.

14 What is extraction ratio? Define clearance, total body clearance and organ clearance.

15 Describe the method of residuals for determination of absorption rate constant. **OR** What do you mean by method of residuals? Draw an illustrative diagram for that.

16 Enlist the methods for determination of absorption rate constant and explain any one in detail

17 Discuss Wagner- Nelson and Loo-Riegelman method.

18 Write a note on Wagner Nelson method for pharmacokinetics of drug absorption.

19 What are loading and maintenance dose? How are they calculated? **OR** Explain calculation of loading and maintenance dose with examples.

NON-LINEAR PHARMACOKINETIC

1 What processes of ADME are known to show non-linearity? Give examples. OR Explain causes of non-linearity.

2 What is non-linear pharmacokinetic? Describe the equation that governs the non-linear pharmacokinetics.

3 Write short note on Michaeles Menton equation.