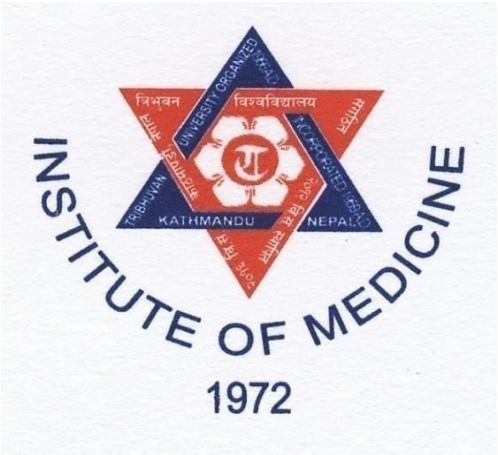
Curriculum

on

Bachelor in Pharmacy

(B. Pharm)



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INSTITUTE OF MEDICINE

NATIONAL CENTRE FOR HEALTH PROFESSIONS EDUCATION

Maharajgunj, Kathmandu, Nepal

2020 (2076

BIOPHARMACEUTICS & PHARMACOKINETICS

Subject: Theory	Year: Second	Code: BP 503 A
Full Marks: 100	Total Teaching hours: 90	Credit hour: 6

Course Description: This subject is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of Biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

General objectives:

At the end of the course, the student will be able to

- **a.** Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and excretion.
- **b.** Explain mechanisms of drug absorption, distribution, metabolism & excretion.
- **c.** Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutics parameters.
- **d.** Critically evaluate biopharmaceutic studies involving drug product equivalency.
- **e.** Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

Specific objectives:

Unit 1: Introduction to Biopharmaceutics and Pharmacokinetics: [3 Hrs]

After the completion of the course, students will be able to

a Define different terminologies of Biopharmaceutics and Pharmacokinetics

b Discuss fundamental principles and their role in formulation development and clinical setting

c Discuss the Significance of plasma drug concentration measurement and plasma concentration time profile

Unit 2: Drug absorption: [7 Hrs]

After the completion of the course, students will be able to

a Discus Physiology of cell membrane

b Explain mechanism of drug absorption

c Mention factors affecting drug absorption

Unit 3: Drug distribution: [5 Hrs]

After the completion of the course, students will be able to

a Explainthe processes and patterns of drug distribution in the body

b Explain the concept of apparent volume of distribution and its significance

c Disucss the factors affecting drug distribution

d Disucss protein-drug binding and factors affecting protein-drug binding

e Show the clinical significance of protein-drug binding and drug displacement interactions

f Discuss the kinetics of protein-drug binding.

Unit 4: Drug metabolism: [4 Hrs]

After the completion of the course, students will be able to

a Discuss the consequences of drug metabolism

b Discuss thefactors affecting drug metabolism;

c Describe the phases of drug metabolism.

Unit 5: Drug excretion: [5 Hrs]

After the completion of the course, students will be able to

a Disucss the ypes of drug excretion

b Discuss renal drug excretion

c Discuss the concept of clearance

d Explain the mechanism of renal clearance

e Mention non-renal routes of drug excretion

f Explain the extraction ratio

g Discussthe first–pass effect

h Discuss hepatic clearance, biliary excretion; and enterohepatic circulation.

Unit 6: Drug interaction:[4 Hrs]

After the completion of the course, students will be able to

a Discuss the types of drug interaction

b Discuss the significance of pharmacokinetic drug interaction in combination therapy

c Explain the factors affecting drug interaction; measures to prevent drug interaction.

Unit 7: Compartment kinetics[15 Hrs]

After the completion of the course, students will be able to

a Discuss One and Two compartment models

b Analyze pharmacokinetic data from plasma and urine data after administration by intravascular (bolus and infusion) and extravascular routes

c Diffrentiate between zero and first order processes

d Discussthe determination of absorption rate constant by Residual method

e Dintinguish between zero and first order absorption rate constant by using Wagner-Nelson and Leo-Reigelman method

f Discuss AUC and its significance

g Discuss the treatment of urinary excretion data (rate of excretion and Sigma minus plot)

h Discuss the curve fitting and regression procedures.

Unit 8: Dissolution studies [10 Hrs]

After the completion of the course, students will be able to

a Define the concept of dissolution

b Discuss theories of dissolution
c Discuss Biopharmaceutics classification system and its application
d Discuss in-vitro dissolution studies
e Discuss the concepts on various mathematical modeling of drug release
f Explain in-vitro in-vivo correlation.

Unit 9: Bioavailability and bioequivalence [12 Hrs]

After the completion of the course, students will be able to

a Dintinguish Relative and absolute bioavailability
b Discuss the methods of determination of bioavailability using blood level and urinary excretion data following both intravascular and extravascular administration
c Discuss the measures to enhance bioavailability
d Explain design of single dose bioequivalence study and relevant statistics
e Discuss the regulatory requirement for conduction of bioequivalence studies
f Discuss Biowaivers.

Unit 10: Non-linear pharmacokinetics [8 Hrs]

After the completion of the course, students will be able to

a Discuss Non-linear pharmacokinetics with special reference to one compartment model after i.v. bolus administration
b Explain the causes and detection of non-linearity (saturation mechanism)
c Discuss Michaelis-Menten equation and its significance
d Discuss the different methods to determine k_m and $V_{max.}$

Unit 11: Clinical Pharmacokinetics [12 Hrs]

After the completion of the course, students will be able to

a Discuss Clinical application of pharmacokinetic principles
b Explain individualization of dosage regimen
c Mention altered kinetics in pregnancy, child birth, infants and geriatrics, liver, and renal diseased states.
d Discucss Indications and Protocol for TDM
e Discuss application of biopharmaceutics and pharmacokinetics in controlled release drug delivery system.

BIOPHARMACEUTICS & PHARMACOKINETICS

Subject: Practical	Year: Second	Code: BP 503 B
Full Marks: 50	Total Teaching hours: 90	Credit hour: 2

At the end of the course, students will be able to

1. Perform in-vitro dissolution studies of various dosage forms (conventional and controlled release)
2. Determine Ka, Ke, $t_{1/2}$, C_{max}, and T_{max} after i.v. bolus, i.v infusion and extravascular administration of various dosage forms.
3. Perform comparison of dissolution studies of two different conventional marketed products of same drug
4. Perform protein binding studies of a highly and poorly protein bound drug.
5. Perform calculation of bioavailability from urinary excretion data from thegiven data experiments
6. Perform Pharmacokinetic study of drug using salivary data
7. Perform calculation of AUC and bioequivalence from thegiven data
8. Demonstrate influence of polymorphism on solubility.
9. Demonstrate influence of polymorphism on dissolution.
10. Determine dosage adjustment in pediatric, geriatric, renal failure and hepatic failure patients
11. Determine dosages in the formulation of controlled release drug delivery systems
12. Calculation of absorption rate constant by of Wagner-Nelson method
13. Demonstrate Bioequivalence testing of drug products (Using published Literature)
14. Develop IV-IV correlation : case studies
15. Perform Computer Simulations in Pharmacokinetics and Pharmacodynamics.
16. Perform Computational Modeling Of Drug Disposition

Reference books (Latest Editions)

1. Notari R.E, Biopharmaceutics and Pharmacokinetics – An introduction. Marcel Dekker Inc. N.Y.
2. Wagner J.G. Pharmacokinetics for the Pharmaceutical Scientist. Technomic Publishing A.G
3. Notari R. F.Biopharmaceutics and Pharmacokinetics.
4. Shargel L. Applied biopharmaceutics and pharmacokinetics. Prentice-Hall Inernational edition.USA
5. Brahmankar D. M, Jaiswal S. B.Bio pharmaceutics and Pharmacokinetics-A Treatise. Vallabh Prakashan Pitampura, Delhi
6. Rowland M. Clinical Pharmacokinetics, Concepts and Applications.