DEPARTMENT OF PHARMACY

M.I.T., MUZAFFARPUR

AFFILIATED TO

ARYABHATTA KNOWLEDGE UNIVERSITY,

MITHAPUR, PATNA

NAME OF FACULTY: MRS. SWATI
DEPARTMENT OF PHARMACY,
M.I.T. MUZAFFARPUR
Contact Details:
Email ID

NAME OF COURSE: PHARMACOGNOSY IV
COURSE CODE (T): 1601
COURSE CODE (P): 1601P
SEMESTER:
ACADEMIC: 2018-2019

PHARMACOGNOSY -IV

B. PHARM – FIFTH SEMESTER

1. Course Syllabus

Module-1

1. Introduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting.

2. Biopharmaceutics: a) Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion and pinocytosis). b) Factors influencing absorption - Physicochemical, physiological and pharmaceutical. c) Drug distribution in the body, plasma protein binding.

Module-2

3.Phamacokinetics : a) Significance of plasma drug concentration measurement. b) Compartment model-Definition and Scope. c) Pharmacokinetics of drug absorption - Zero order and first order absorption rate constant using Wagner - Nelson and Loo- Reigelman method. d) Volume of distribution and distribution coefficient. e) Compartment kinetics - One compartment and two compartment models. f) Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intravascular and oral route. g) Curve fitting (method of Residuals), regression procedures.

h) Clearance concept, Mechanism of renal clearance, clearance ratio, determination of renal clearance. i) Extraction ratio, hepatic clearance, biliary excretion, Extrahepatic circulation. j) Non-linear pharmacokinetics with special reference to one compartment model after intravenous drug administration, Michaeles Menten Equation, detection of non-linearity (Saturation mechanism).

Module-3.

4.Clinical Pharmacokinetics: a) Definition and scope. b) Dosage adjustment in patients with and without renal and hepatic failure. c) Design of single dose bio-equivalence study and relevant statistics. d) Pharmacokinetic drug interactions and their significance in combination therapy.

5. Bioavailability and bioequivalence: a) Measures of bioavailability, Cmax, tmax, and Area under the curve (AUC). b) Design of single dose bioequivalence study and relevant statistics. c) Review of regulatory requirements for conduction of bioequivalent studies.

Recommended Books:

1.Biopharmaceutics and Pharmacokinetics by D.M. Brahmankar and Sunil B. Jaiswal

2. Fundamentals of Biopharmaceutics and Pharmacokinetics by V. Venkateswarulu

3. Biopharmaceutics and Clinical Pharmacokinetics by Notari

4. Biopharmaceutics and Clinical Pharmacokinetics by Gibaldi

5. Applied Biopharmaceutics and Pharmacokinetics by Shargel and Yu

SAMPLE TIME TABLE

MUZAFFARPUR INSTITUTE OF TECHNOLOGY

ODD SEM (JULY- DEC 2018) TIME TABLE FOR 3 rd , 5 th & & 7 th SEMESTER, B.PHARM, WITH EFFECT FROM 16.07.20

DAY	SEMESTER	9 AM TO 10	10 -11 AM	11- 12 AM	12 -1 PM	2- 3 PM	3 P
MON	THIRD SEM	APHE II SK	PHARM ANAL II GT	PHARMACEUTICS III AB	PHARMACOGNOSY II NRB		CLAS
	FIFTH SEM	PHARMACEUTICS V RKC	PHARMACEUTICS V LAB RKC				CLAS
	SEVENTH SEM	PHARMA. BIOTECH SNS	PHARM CHEM VII RP	PHARMA. INDUST. MANAG.	PHARMACOLOGY III RP		CLAS
TUES	THIRD SEM	PHARMACEUTICS III AB	PHARM CHEM IV SW	PHARMACEUTICS III AB(T)	PHARM ANAL II GT(T)		PHARMA LA
	FIFTH SEM	PHARM CHEM V SNS	PHARMACEUTICS VI AB	PHARMA CEUTICS V RKC	PHARMACOLOGY I SK		PHARM C S
	SEVENTH SEM	PHARMACEUTICS VIII RKC	PHARM CHEM VII RP	PHARMACOLOGY III RP	PHARMACEUTICS VIII RKC(T)		PHARMA LA
WED	THIRD SEM		PHARMACOGNOSY II NRB(T)	PHARMACOGONOSY II NRB	PHAR ANAL II GT		PHARMAC II LA
	FIFTH SEM	PHARMACOLOGY I SK	PHARM CHEM V SNS	PHARMACEUTICS VI AB	PHARMACOLOGY I SK(T)		PHARMA LA
	SEVENTH SEM	PHARM CHEM VII RP(T)	PHARMACEUTICS VIII RKC	PHARM CHEM VII RP	ELECTIVE OPT		PHARM C
THURS	THIRD SEM	APHE II SK(T)	PHARM CHEM IV SW	APHE II SK	PHARM CHEM IV SW(T)		PHARM A C

	FIFTH SEM	PHARM CHEM V SNS	PHARMACEUTICS VI AB	PHARMACOGONOSY IV SW		PHARMAC IV LA
	SEVENTH SEM	PHARMACEUTICS VIII RKC	PHARMA. BIOTECH SNS(T)	PHARMACOLOGY III RP	ELECTIVE OPT	ELECTIVE
FRI	THIRD SEM	APHE II SK	PHARMACUTICAL CHEMISTRY IV LAB SW			APHE I
	FIFTH SEM	PHARMACOGONOSY IV SW	PHARMACEUTICS V RKC	PHARMACOGONOSY IV SW(T)	PHARMACEUTICS V RKC(T)	PHARMAC LAB C
	SEVENTH SEM		ELECTIVE OPT (T)	ELECTIVE OPT	PHARMA. BIOTECH.SNS	PHARMA III RK
SAT	THIRD SEM	PHARMACOGONOSY II NRB	PHARM CHEM IV SW	PHAR ANAL II GT	PHARMACEUTICS III AB	
	FIFTH SEM	PHARM CHEM V SNS(T)	PHARMACOLOGY I SK	PHARMACEUTICS VI AB	PHARMACOGONOSY IV SW	
	SEVENTH SEM	PHARMACOLOGY III RP(T)	PHARMA. INDUST. MANAG.	PHARMA. BIOTECH SNS		

2. Program Objectives (POs)

The graduates of the program will possess:

1. The knowledge of core concepts ofIntroduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting.

2. The knowledge of bio pharmaceutics

3. Brief knowledge about pharmacokinetics

4. Brief knowledge about Clinical Pharmacokinetics and Bioavailability and bioequivalence

3. Course Outcomes (COs)

1. Recall The knowledge core concepts ofIntroduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting. The knowledge.
2. The knowledge of biopharmaceutics

3. brief knowledge about pharmacokinetics

4. brief knowledge about Clinical Pharmacokinetics and Bioavailability and bioequivalence

4. Mapping of COs with Pos

PO	CO1	CO2	CO3	CO4
1				

2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

5. Assessment Methods for Cos

5.1. Theory

S. No	Assessment Tools	Marks	Outcomes
1	Sessional Examination	20	CO1 CO2 CO3 CO4

2	Assignment	02	CO1 CO2 CO3 CO4
3	Presentation	02	CO1 CO2 CO3 CO4
4	Quizzes	01	CO1 CO2 CO3 CO4
5	Attendance	05	NA
6	University Examination	70	NA

5.2. Practical

S. No	Assessment Tools	Marks	Outcomes
1	Attendance	05	CO1 CO2 CO3 CO4
2	Experiment valuation	10	CO1 CO2 CO3 CO4
3	Internal Viva- voce	05	CO1 CO2 CO3 CO4
4	University Practical Exam	30	CO1 CO2 CO3 CO4

6. Delivery Methodology

Outcomes	Methods	Supporting Tools

CO 1	Chalk-Talk, Interactive classroom, ICT usage, Case study discussion about diseases, Group discussions, Web based learning	Board, Laptop, Projector, You Tube, WhatsApp, Google,
CO2	Chalk-Talk, Interactive classroom, ICT usage, Case study discussion about diseases, Group discussions, Web based learning	Board, Laptop, Projector, You Tube, WhatsApp, Google,
CO3	Chalk-Talk, Interactive classroom, ICT usage, Case study discussion about diseases, Group discussions, Web based learning	Board, Laptop, Projector, You Tube, WhatsApp Google,
CO4	Chalk-Talk, Interactive classroom, ICT usage, Case study discussion about diseases, Group discussions, Web based learning	Board, Laptop, Projector, You Tube, WhatsApp, Google,

7. Teaching plan

7.1. Theory

Lecture No.	Contents
1	Introduction to Biopharmaceutics and their role in formulation development and clinical setting.
2	Introduction to Pharmacokinetics and their role in formulation development and clinical setting
3	Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion and pinocytosis).
4	Factors influencing absorption - Physicochemical, physiological and pharmaceutical.
5	Drug distribution in the body, plasma protein binding
6	Significance of plasma drug concentration measurement
7	Compartment model-Definition and Scope.
8	Pharmacokinetics of drug absorption - Zero order and first order absorption rate constant using Wagner - Nelson and Loo- Reigelman method
9	Volume of distribution and distribution coefficient
10	Compartment kinetics - One compartment and two compartment models
11	Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intravascular and oral route
12	Curve fitting (method of Residuals)

13	regression procedures
14	Clearance concept, Mechanism of renal clearance
15	clearance ratio
16	determination of renal clearance
17	Extraction ratio, hepatic clearance
18	biliary excretion, Extrahepatic circulation
19	Non-linear pharmacokinetics with special reference to one compartment model after intravenous drug administration
20	Michaeles Menten Equation
21	detection of non-linearity (Saturation mechanism)
22	Clinical Pharmacokinetics: a) Definition and scope
23	b) Dosage adjustment in patients with and without renal and hepatic failure
24	c) Design of single dose bio-equivalence study and relevant statistics
25	d) Pharmacokinetic drug interactions and their significance in combination therapy.
26	Bioavailability and bioequivalence
27	a) Measures of bioavailability, Cmax, tmax, and Area under the curve (AUC).
28	b) Design of single dose bioequivalence study and relevant statistics
29	c) Review of regulatory requirements for conduction of bioequivalent studies.

7.2. Practical

Exp. No	Experiment
1	Experiments designed for the estimation of various pharmacokinetic parameters with given data
2	Analysis of biological specifications for drug content and estimation of the pharmacokinetic parameter
3	In vitro evaluation of different dosage forms for drug release
4	Absorption studies - in- vitro and in -situ.
5	Statistical treatment of pharmaceutical data.