

Model (No 12)

Course Specification: Biopharmaceutics & Pharmacokinetics

Faculty of Pharmacy

Farabi Quality Management of Education and Learning - 23/11/2020

University :Mansoura University
Faculty :Faculty of Pharmacy

Department:

1- Course data :-

Code:	PT416						
Course title:	Biopharmaceu	Biopharmaceutics & Pharmacokinetics					
Level:	Four	Four					
Program Title:	pharmaceutical sciences						
Specialization:	Major						
Teaching Hours: Theoretical: 2 Tutorial:					Practical:	1	

2- Course aims :-

- 1. Understanding the principle of biopharmaceutics in all pharmacokinetic parameters.
- 2. Solving problems related to the pharmacokinetic parameters(including AUC,half life,total clearance,volume of distribution)
- 3. Covering the principles of pharmacokinetic (including absorption ,distribution ,metabolism ,and elimination)and drug-drug interactions
- 4. Knowing the basis of selection a particular drug preparation ,route of administration and evaluation of bioavailability of dugs products

3- Intended learning outcomes of course (ILO'S) :-

a- Knowledge and understanding

- 1. [a7] Describe the basics of pharmacokinetics and biopharmaceutics and their application in therapeutic drug monitoring (TDM), dose modification and bioequivalence studies.
 - o a7.1-Define the biopharmaceutical topics such as: drug absorption ,distribution ,metabolism

,excretion

- a7.2-Understanding the various factors affecting the bioavailability of drugs such as:
 physicochemical factors
- a7.3-Calculate pharmacokinetic parameters from data obtained for drugs administered via the intravascular and extravascular routes
- a7.4-Describe a route of administration with a dosage regimen that gives appropriate response
- a7.5-Understand the physicochemical properties of the drugs

b- Intellectual skills

- 1. [b10] Adjust dosage and dose regimen of medication based on pharmacokinetic principles.
 - b10.1-Estimate the different pharmacokinetic parameters from the supplied biological data
 - b10.2-Select the most suitable dosage form for drug that gives the higher bioavailability
 based on the properties of the drug and excipients
 - b10.3-Point out the application of these pharmacokinetic principles to the therapeutic management of patients
- 2. [b23] Define the order of the reaction, calculate the half-life time, rate of reaction and predict the expiration date of the drug.
 - o b23.1-Close the most suitable conditions for drugs taking to achieve high bioavailability

c- Professional and practical skills

- [c13] Assess risks concerning drug-drug interaction, adverse reaction and incompatibilities in different pharmaceutical preparations.
 - o c13.1-Follow-up in-vitro/in-vivo correlation of the drug in the body
 - c13.2-Validate different bioavailability types
 - o c13.3-Calculate a dosage regimen
 - c13.4-Interpret the absolute and relative bioavailability of a drug through plasma and urinary excretion data

d- General and transferable skills

- 1. [d10] Support patient, pharmaceutical and health care
 - \circ d10.1-Disseminate information about the importance of bioavailability of drug materials
 - o d10.2-Analyze drug data for probability of differences in therapeutic effectiveness

4- Course contents :-

No	Topics	Week
1	Introduction to biopharmaceutics and pharmacokinetics definitions	1
2	Pharmacokinetic parameters and sites of drug administration	2
3	Pharmacokinetic oral route and absorption introduction	3
4	IV infusion and mechanism of drug absorption	4
5	Multiple dosing and factors affecting drug absorption	5
6	Bioavailability assessment and introduction to drug distribution	6
7	Week 7 Mid-term	7
8	Physicochemical properties affecting bioavailability (solubility, particle size, surface area)	8
9	Physicochemical properties affecting bioavailability (partition coefficient ,in situ salt formation) and factors affecting distribution	9
10	Physicochemical properties affecting bioavailability (in situ micronization, complexation ,polymorphism) and introduction to drug elimination	10
11	Physicochemical properties affecting bioavailability(Noyes Whitney equation ,chemical stability , micellar solubilization) and methods of drug elimination & Drug metabolism	11

5- Teaching and learning methods:-

s	Method	Knowledge and understanding	Intellectual skills	Professional skills	General skills
1	Lectures using white board and data show.	a7.1,a7.2,a7.3,a7.4,a7.5	b10.1,b10.2,b23.1		
2	Practical session using laboratory	a7.3,a7.4	b10.1,b10.2	c13.1,c13.2,c13.3,c13.4	d10.1,d10.2

oquinment		
equipilient		

6- Teaching and learning methods of disables :-

1. none

7- Student assessment :-

a- Student assessment methods

No	Assessment Method	Knowledge and understanding	Intellectual skills	Professional skills	General skills
1	1-Written exam	a7.1,a7.2,a7.3,a7.4,a7.5	b10.1,b10.2,b23.1		
2	2-Practical exam	a7.3,a7.4	b10.1,b10.2,b10.3,b23.1	c13.2,c13.4	
3	3-Oral	a7.1,a7.2,a7.3,a7.4,a7.5	b10.1,b10.2,b23.1		d10.1,d10.2

b- Assessment schedule

No	Method	Week
1	Practical	11th week
2	Mid-term	7th week
3	Oral	14th week
4	Written	14th week

c- Weighting of assessments

No	Method	Weight
1	Mid-term examination	10%
2	Final-term examination	50%
3	Oral examination	15%
4	Practical examination & Semester work	25%
Tota	al	100%

8- List of references

S	Item	Туре
1	British Pharmacopoeia, Vol., I, 1st Ed., The Stationery Office, London, U. K., (2010)	Course notes
2	Martindale, The complete Drug Reference,35th Ed.,sweetman,S.C.,ed.The pharmaceutical press,London,U.K.(2007)	Books

3	3	Basic pharmacokinetics by Mohsen A Hedaya (2007)	Open books
4		Applied Biopharmaceutics and Pharmacokinetics, 5 th Edition by Madjackfrost(2010)	Open books

9- Matrix of knowledge and skills of the course

S	Course contents	Knowledge and understanding	Intellectual skills	Professional skills	General skills
1	Introduction to biopharmaceutics and pharmacokinetics definitions	a7.1	b10.1		d10.2
2	Pharmacokinetic parameters and sites of drug administration	a7.4	b10.1		d10.2
3	Pharmacokinetic oral route and absorption introduction	a7.1	b10.1		d10.2
4	IV infusion and mechanism of drug absorption	a7.3	b10.1,b10.3		d10.2
5	Multiple dosing and factors affecting drug absorption	a7.3	b10.1,b10.3		d10.2
6	Bioavailability assessment and introduction to drug distribution	a7.1	b10.1,b23.1	c13.2,c13.4	d10.2
7	Week 7 Mid-term				d10.1,d10.2
8	Physicochemical properties affecting bioavailability (solubility, particle size, surface area)	a7.2,a7.5	b10.2,b23.1	c13.2	d10.1
9	Physicochemical properties affecting bioavailability (partition coefficient ,in situ salt formation) and factors affecting distribution	a7.2,a7.5	b10.2	c13.2	d10.1
10	Physicochemical properties affecting bioavailability (in situ micronization, complexation ,polymorphism) and introduction to drug elimination	a7.2,a7.5	b10.2	c13.2	d10.1
11	Physicochemical properties affecting bioavailability(Noyes Whitney equation ,chemical stability , micellar solubilization) and methods of drug elimination & Drug metabolism	a7.1,a7.2,a7.5	b10.2,b23.1	c13.2	d10.1

Course Coordinator(s): -

Noha Mohamed Saleh ELmetwaly Marae

Head of department: -

Osama abdelAzeem Soliman