Course Outline

Course Code: PHR 307
Course Title: Biopharmaceutics-I
Assigned Faculty and their class schedule:

Assigned Faculty	Day	Time	Email ID
Dr. Abu Sara Shamsur Rouf	Monday	10.50-11.40 am	rouf321@yahoo.com
Dr. A K Lutful Kabir	Sunday	9.50-10.40 am	aklkabir@gmail.com
Nusrat Ahmed			nusrat.9208@gmail.com
Md. Mahbubul Alam			mahabub22du@gmail.com

Course Aim:
To help students grasp the basic theories of biopharmaceutics and pharmacokinetics and develop the practical knowledge for future pharmaceutical research.

Outcome:

- Understand the basic concepts of kinetic behavior of drug molecules in biological system.
- Determine the basic pharmacokinetic parameters influencing drug absorption
- Identification of the biological, physicochemical and dosage form related factors affecting gastrointestinal absorption of drugs
- Outline the basic principles of hepatic and renal drug elimination
- Significance of plasma drug concentration-time profile curve
- Necessity of bioavailability and bioequivalence study of drug products for safety concern.
- Assess practical examples and situations applied in patient care and drug consultation situations.

Format and Procedures:

- Lectures will be delivered on all the topics of the course with comprehensive explanation of all the contents of the topics using Power Point presentation as well as by writing on the white board. Relevant videos will be showed which will aid to the complete understanding of any topic.
- At the end of each class there will be an interactive session to find out whether the students were able to grasp the key points of each lecture.
- Students will be divided into groups (number depending on the number of students in class) to analyze and find answer to a critical question or two-three case study will be given that will require brainstorming of students.
- A briefing on the relevant lab pertaining to the course will also be done during the class so that the students can relate the theory to the practical work done in the laboratory.

- Assignments and oral presentation will be given to all the students and each student will have different topics to assess their level of understanding.

Incourse:
Total mark allocated for incourse is 20. Two incourses will be taken and average of these 2 incourses will be counted. There will be no makeup incourse. Incourses will be taken on below mentioned oral presentations topics.

Final Examination:
Final examination will be of 80 marks. The length of the final examination will be 4 hours. MCQ will be taken of 20 marks for first 20 minutes and rest of time will be allocated for written exam which is of 60 marks.

Oral presentation:
Oral presentation will be given to enhance the student's ability to familiarize with the course.

1. Generic products vs. innovator products
2. Trade products vs. innovator products and Bangladesh prespective
3. Necessity of bioequivalence study of pharmaceuticals
4. Bioequivalence vs. biowaivers of pharmaceuticals
5. Regulatory aspects of bioequivalence study
6. Polymorphism vs. bioavailability
7. Physical nature of drugs vs. bioequivalence
8. Importance of analytical skills for bioequivalence study
9. Mechanism of drug transport

Final Grading:
Marks earned by the students in incourse, final examination will be cumulated and the total is to be graded as per University of Dhaka regulation.

Reference Books:

a) Applied Biopharmaceutics & Pharmacokinetics- Leon Shargel and Andrew B.C. Yu, 7th edition, McGraw-Hill Education.
b) Biopharmaceutics and Clinical Pharmacokinetics- Milo Gibaldi, 4th edition, Lea & Febiger.

Tentative Course Schedule

Chapters	Topics to be discussed	Number of classes required	Assigned Faculty
Chapter 1 Introduction of pharmacokinetics and biopharmaceutics		3	ASSR
Chapter 2 Gastrointestinal absorption of drugs:	**Biological consideration**- Membrane physiology, gastrointestinal physiology, mechanism of absorption etc. **Physicochemical consideration-** pKa and gastrointestinal absorption, pH partition theory and other physicochemical factors. **Dosage form consideration**- Role of different dosage forms like solution, suspension, tablet, capsule, emulsion etc. on gastrointestinal absorption. **Disintegration and dissolution of drugs.**	10-12	ASSR
Chapter 3 Distribution of drugs	Important Pharmacokinetic parameters such as biological half-life, apparent volume of distribution, area under the curve, elimination rate constant etc. Interpretation of drug-plasma level curve. **Drug-protein interaction**- Theoretical aspect of protein-drug interaction, methods used for protein binding, identification of drug binding sites, kinetics of protein binding, determination of binding sites and association constant, factors affecting protein binding, effects of protein binding on drug distribution, elimination and pharmacological effects of drugs.	8-10	AKLK
Chapter 4 Drug clearance	Theoretic aspects of drug elimination, excretion and biotransformation. **Renal elimination**: Glomerular filtration, active tubular secretion, tubular reabsorption, determination of renal clearance. **Hepatic elimination:** Biotransformation of drugs, drug biotransformation reactions, pharmacokinetics of drugs and metabolites (Michelis Menten Equation), first pass effect, liver excretion ratio, relation between absolute bioavailability and liver excretion, hepatic clearance- relationship between blood flow, intrinsic clearance and hepatic clearance, Hepatic clearance of a protein bound drug (effect of protein binding on hepatic clearance).	6	NA

	Biliary excretion of drugs.		
Chapter 5 Bioavailability and bioequivalence	Definitions of different parameters relative to bioavailability; purpose of bioavailability, relative and absolute bioavailability, methods of determining bioavailability, criteria for bioequivalence studies.	7	MAB
Chapter 6 Drug product selection on the basis of bioavailability testing.		7	MAB
Oral Presentation	On Given topics	16 (extra classes)	