Name of the Programme : M.Sc. Part-II (Biochemistry)
Course Code : CHB-623
Title of the Course : Drug metabolism and Pharmaceutics
Number of Credits : 4
Effective from AY : 2022-23

Prerequisites for the Course:	Students should have studied natural and life sciences at M.Sc. Part I Level	
Course Objectives:	1. To introduce concepts of drug administration, distribution, metabolism and excretion. 2. To introduce the students to pharmacopoeia, and types of drug formulations. 3. To acquaint the students with GMP and quality control practices in a pharmaceutical set-up.	
Content:		**No of hours**
	1. Drugs Absorption and distribution in human body: a. Definition and types of drugs (therapeutic, drugs of abuse, poisons). b. Introduction to pharmacokinetics and pharmacodynamics. c. Routes of drug administration, introduction to absorption, distribution, metabolism, and excretion (ADME) of drug. d. Absorption and distribution of drug through organ /tissue. e. Factors affecting drug distribution: Physicochemical properties of drugs, organ/tissue size, blood flow to the organ, physiological barriers to the distribution of drugs, drug binding blood/ tissue/ macromolecules. f. Protein/tissue binding of drugs – factors affecting protein binding of drugs, significance and kinetics, tissue binding of drugs.	**8**
	2. Drug Metabolism a. Biotransformation of drugs and factors affecting biotransformation. Organs of drug metabolism: hepatic and extrahepatic metabolism. b. Mechanisms of drug metabolism – inactivation, bioactivation, reactive intermediates. c. Phase 1 reactions - CYP-Catalyzed: Hydroxylation (Primarily at C, N, some at S), Dealkylation (N- and O-dealkylation), Deamination, Epoxidation, Reduction. Non-CYP-Catalyzed: Oxidation (Alcohol and Aldehyde Dehydrogenase, Flavin-Containing Monooxygenase, Monoamine Oxidase), Reductase (Quinone Reductase), Hydrolysis (Esterases, Amidases, Epoxide Hydrolase). d. Phase 2 reactions -Glucuronidation, Sulfation, Acetylation, Glycine conjugation (minor), Glutathione conjugation (toxic	**9**

	substances). e. Significance of drug metabolism (paracetamol/aspirin/ ibuprofen/ antibiotics).	
	3. Excretion of drugs a. Renal excretion, factors affecting renal excretion. b. Non renal routes of excretion, factors affecting excretion and enterohepatic circulation.	**2**
	4. Posology a. Determination of doses; dose response relationship, dosage form design, biopharmaceutical consideration. b. Drug antagonism and drug–drug interaction.	**3**
	5. Drug Extraction a. Solvents used in extraction of drugs, processes used for extraction (infusion, decoction, maceration, percolation, hot extraction). b. Water as a universal pharmaceutical vehicle.	**5**
	6. Types of formulations: a. Tablets: advantages of tablets; types of tablets: effervescent, lozenges, chewable, buccal and sublingual, dispersible, orodispersible, soluble; excipients in tableting, coating in tablets. b. Granulation: methods and equipment, direct compression. c. Sustained release: Delayed absorption and/or a mixture of slow- and fast-release particles to produce rapid and sustained absorption in the same dose. d. Capsules: hard gelatin and soft gelatin capsules- differences and composition, advantages and limitations, Excipients in capsule. e. Liquids and Gels: Types of liquid formulations, excipients including solubilizers, stabilizers, buffers, tonicity modifiers, bulking agents, viscosity enhancers/reducers, surfactants, chelating agents and adjuvants, hydrophilic-lipophilic balance (HLB) values. f. Parenterals: Intravenous, subcutaneous, intramuscular or intra articular administration, stored in liquid form, or in lyophilized form if unstable. g. Topical: Cream, ointment, gel, paste, powder.	**12**
	7. Quality assurance/ Quality control a. Introduction to GLP, GMP and SOPs Raw material analysis (RMA), Quality control of pharmaceutical excipients. b. Packaging material testing (PMT): Permeability of plastic; testing of foil, bottles, carrions. Limit tests – chloride, sulphate, arsenic, lead, iron, nitrate, alkali and alkaline earth	**12**

	metals Limits of insoluble matter, soluble matter, nonvolatile matter, volatile matter, residue on ignition and ash value. c. Sources of contamination in pharmaceutical compounds (as per Pharmacopoeia). d. Physico-chemical and microbiological analyses of formulations. e. Types of errors, selection of sample, precision and accuracy.	
	8. Drug Stability a. Solid state, solution phase physical stability testing, Stability testing general protocol, climatic zones, reference to regulatory requirements (ICH guidelines). b. Kinetic principles applied for stability evaluation and their applications in predicting shelf life, accelerated stability study and shelf life assignment. c. Forced degradation studies.	**5**
	9. Research and Development a. Introduction to drug design b. Drug discovery and development c. Clinical trials	**4**
Pedagogy	Mainly lectures and tutorials. Seminars / term papers /assignments / presentations / self-study or a combination of some of these can also be used. ICT mode should be preferred. Sessions should be interactive in nature to enable peer group learning.	
References / Readings:	1. Brunton, L. L., Hilal-Dandan, R., Knollmann, B. C.; Goodman & Gilman's: The Pharmacological Basis of Therapeutics, McGrawHill Education, 2018, 13th Edition. 2. Mahato R. I., Narang A. S., Pharmaceutical Dosage Forms and Drug Delivery: Revised and Expanded, CRC Press, 2017, 3rd Edition. 3. Aulton, M. E., Pharmaceutics: The Science of Dosage Form Design, Churchill Livingstone; 1988, 7th edition. 4. Aulton, M. E., Taylor, K.; Aulton's Pharmaceutics: The Design and Manufacture of Medicines, Elsevier, 2017, 5th Edition. 5. Allen, L., Popovich, N. G., Ansel, H.; Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincott Willimas & Wilkins, 2018, 11th Edition	
Course Outcome:	1. Students will be able to explain the basic pathways of drug distribution, metabolism and excretion in the body. 2. Students will be able to categorize different types of drug formulations and their contents. 3. They will be able to implement quality assurance and quality control procedures for drug formulations.	

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