

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm
SEMESTER: VIII

Subject Name: Dosage form Design II

Subject Code: 2280001

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

No	Course Content	Hrs
1	<p>Controlled and sustained release dosage forms Design of oral sustained release systems: Biological factors, Physicochemical factors Diffusional systems: -Reservoir system, Lag time, Burst effect, Matrix system, Effect of porosity and tortuosity Dissolution controlled system, Cube route dissolution equation, Diffusion layer controlled dissolution. Bioerodible and Combination of diffusion and dissolution systems. Design, development and evaluation of oral and parenteral controlled release formulations.</p>	8
2	<p>Novel drug delivery system (a) Modified drug delivery systems: Fundamentals, rational of modified release drug delivery, factors influencing the design and performance, pharmacokinetic and pharmacodynamic basis for modified drug delivery systems, estimation of loading and maintenance dose. (b) Design and development of oral modified release dosage forms: Matrix tablets, microspheres, hydrogels, osmotic pressure controlled systems, gastro retentive systems, colon targeting. (c) Fabrication of parenteral drug delivery systems: Parenteral emulsions & parenteral suspensions, microspheres, liposomes, niosomes, nanoparticles. (d) Formulation and evaluation of Transdermal drug delivery systems. (e) A brief study of site specific and targeted drug delivery systems, transmucosal and ocular drug delivery systems.</p>	22
3	<p>Pharmacokinetics (a) Definition and scope, significance of plasma drug concentration measurement. (b) Compartment model: Phamacokinetics of drug absorption Zero order and first order absorption rate constant using Wagner-Nelson and Loo-Riegelman method. (c) Volume of distribution and distribution coefficient. (d) Compartment kinetics-one compartment and two compartment models. Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intra vascular and oral route. (e) Curve fitting (Method of Residuals), regression procedures. (f) Clearance concept, mechanism of renal clearance, clearance ratio, determination of renal clearance. (g) Hepatic elimination of drugs, first pass effect, extraction ratio, hepatic clearance, biliary excretion, extrahepatic circulation. (h) Non-linear pharmacokinetics with special reference to one compartment model after I.V. drug administration, Michaelis Menten Equation, detection of nonlinearity (Saturation mechanism). (i) Numericals related to pharmacokinetic parameters using one compartmental model.</p>	10
4	<p>Clinical Pharmacokinetics a) Definition and scope b) Dosage adjustment in patients with and without renal and hepatic failure. c) Pharmacokinetic drug interactions and their significance in combination therapy</p>	5

Practical – 22800P1

1.	Preparation and evaluation of matrix tablet of BCS class I drug with erosion and diffusion based mechanisms.
2.	Preparation and evaluation of tablet coating
3.	Preparation and evaluation of osmotic drug delivery system
4.	Preparation and evaluation of floating drug delivery system
5.	Preparation and evaluation of buccal tablet
6.	Preparation and evaluation of buccal film
7.	Preparation and evaluation of transdermal patch
8.	Preparation and evaluation of colon drug delivery system
9.	Preparation and evaluation of Sodium alginate beads
10.	Preparation and evaluation of in situ gel
11.	Preparation and evaluation of microparticles by solvent change method
12.	Calculation of absorption rate by residual method
13.	Calculation of absorption rate by Wagner Nelson method
14.	Calculation of elimination rate by urinary excretion method

References Books:

- 1 Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel, Susanna Wu-Pong and Andrew B. C. Yu.
- 2 Pharmacokinetics by Milo Gibaldi and Donald Perrier
- 3 Remington's Pharmaceutical Sciences, Mack Publishing Company, Easton, Pennsylvania.
- 4 Clinical Pharmacokinetics: Concepts and Applications by Rowland and Tozar, Lippincott Williams & Wilkins.
- 5 Controlled Drug delivery, Fundamentals and Applications by J.R. Robinson & Uinvent Lee, Marcel Dekkar Inc.
- 6 Noval Drug Delivery Systems by Y. W. Chian Ed. James Swarbrick, Marcel Dekker.
- 7 Hanbook of Pharmaceutical excipients, Royal society of Great Britain, U.K. Stability Studies, Marcel Dekker.