GUJARAT TECHNOLOGICAL UNIVERSITY
BACHELOR OF PHARMACY
Semester: VII

Subject Name: **Dosage Form Design- I**
Subject Code: **270001**

[THEORY]

Sr. No	Course Content	Total Hrs.
1.	**Preformulation studies:** a) Study of physical properties of drug like physical form, particle size, shape, density, wetting, dielectric constant, solubility, dissolution and organoleptic property and their effect on formulation, stability and bioavailability. b) Study of chemical properties of drugs like hydrolysis, oxidation, reduction, polymorphisms, racemization, polymerization etc., and their influence on formulation and stability of products. c) Study of prodrugs in solving problems related to stability, bioavailability and elegance of formulations.	**11**
2.	**Pharmaceutical necessities:** Efffect of following adjavunts on formulation of different pharmaceutical products: Antioxidants, preservatives, colours, flavours, diluents, binders, disintigrants, antifirctional agents, emulsifiers, suspending agents, ointment bases, solvents etc. and other formulation additives.	**6**
3.	**Stabilityof pharmaceuticals:** a) Kinetic principles and stability testing: Reaction rate and order, acid base catalysis, decomposition reactions and stabilization of pharmaceuticals. b) Stability of formulation, factors affecting formulation stability, MKT, climatic zones, matrixing and bracketing instability study, accelerated stability testing, real time stability. Current WHO, USFDA and stability testing as per ICH guidelines for pharmaceutical drug substances and drug products. c) Product stability: Requirements, shelf-life, overages, containers, closures. d) Overage calculations	**8**
4.	**Biopharmaceutics:** a) Introduction to biopharmaceutics and its role in formulation development.	**10**

	b) Passage of drugs across biological barriers (passive diffusion, active transport, facilitated diffusion and pinocytosis). c) Factors influencing absorption- physiochemical, physiological and pharmaceutical. d) Drug distribution in the body, plasma protein binding and drug excretion.	
5.	**Bioavailability and Bioequivalence:** a) Measures of bioavailability, Cmax, tmax and area under the curve (AUC). b) Design of single dose bio-equivalence study and relevant statistics. c) Review of regulatory requirements for conduction of bio-equivalent studies.	**5**
6.	**Introduction to BCS and dissolution study:** Definition: BCS, Dissolution mechanisms, Factors affecting dissolution, Intrinsic dissolution rate measurement, Dissolution apparatus for various dosage forms, Dissolution profile comparison using model independent method (similarity factor, dissimilarity factor).	**5**

[PRACTICAL]

1	Determination of the angle of repose, Carr's index, Hausner's ratio of given powder/ granules.
2	Determination of solubility of given drug at different pH
3	To study the compression characteristic of different diluents.
4	To optimize the concentration of suspending agents.
5	To optimize the concentration of emulsifying agents.
6	To study the effect of various binders on performance of tablet.
7	To study the effect of various disintigrants on performance of tablet.
8	To evaluate the physical stability of emulsion and compare with marketed product.
9	To evaluate the physical stability of suspension and compare with marketed product
10	To study the Influence of temperature on the stability of aspirin/ ascorbic acid solution.
11	Compendial dissolution testing and data evaluation for given tablets and capsules.
12	In-vitro dissolution profile comparison of given tablet with reference product using similarity and dissimilarity factor.
13	Enhancement of solubility of poorly water soluble drug by solid dispersion.
14	Enhancement of solubility of poorly water soluble drug by β-Cyclodextrin complexation.
15	Preformulation studies including drug-excipient compatibility studies.
16	Calculation of bioavailability parameters from the given pattern of drug absorption from oral & IV formulations.

Text Books:

1. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel, Susanna Wu-Pong and Andrew B. C. Yu.

Reference Books:

1. The Theory and Practice of Industrial Pharmacy by L Lachman, H Lieberman and J Kanig.
2. Pharmaceutical Preformulation by Carstensen JT, Technomic Publishing Company, Inc., New Holland Avenue, Lancaster, Pennysylvania, USA.
3. Remington's Pharmaceutical Sciences, Mack Publishing Company, Easton, Pennsylvania.
4. Pharmacokinetics by Milo Gibaldi and Donald Perrier.
5. Hanbook of Pharmaceutical excipients, Royal society of Great Britain, U.K.
6. Stability Studies, Marcel Dekker.
7. Pharmaceutical dissolution testing by Umesh V. Banker, Marcel Dekker Inc.