ADVANCES IN PHARMACEUTICAL TECHNOLOGY

UNIT - I Bioavailability and Bioequivalence: Definition, objectives, considerations in in-vivo bioavailability study design, objectives for bioequivalence studies, types of bioequivalence studies, measurement of bioavailability, correlation of in-vitro dissolution & in-vivo bioavailability (IVIVC), methods for enhancement of bioavailability. Biopharmaceutical factors influencing the dosage form design.

UNIT - II Dissolution: BCS classification system, theories of drug dissolution, study of various approaches to enhance dissolution of poorly water soluble drugs, in-vitro drug dissolution testing models for different dosage forms based on USP, modeling and comparison of dissolution profiles using model independent and model dependent approaches.

UNIT - III Topical drug delivery: Advantages and limitations, basic components and approaches used in development of transdermal drug delivery and evaluation of transdermal drug delivery. Ocular drug delivery: Characteristics, formulation approaches, ophthalmic inserts.

UNIT - IV Tablets: Types of tablets, advantages, disadvantages, components, granulation techniques, processing problems during granulation and evaluation of tablets. Tablet coating: sugar coating, film coating and aqueous film coating, problems during processing of tablets and evaluation of tablets.

UNIT - V Drug stability: Pre-formulation studies as per ICH guidelines, stability testing protocol, methods of accelerated stability testing in dosage forms, freeze-thaw methods, centrifugal methods, temperature and humidity control, stability studies as per ICH, WHO guidelines, classification of solvents as per ICH guidelines, drug excipient compatibility and incompatibility studies using DSC, XRD and IR.

UNIT - VI Vesicular systems: Classification, preparation methods, characterization and therapeutic applications of nanoparticles, neosomes, self emulsifying drug delivery systems (SEDDS), self micro emulsifying drug delivery systems(SMEDDS) and liposomes. Drug targeting: Concepts of targeting, passive targeting, active targeting, first, second and third order targeting, targeting to a tumor.

UNIT - VII Mucoadhesion: Definition, mucoadhesion, advantages, disadvantages, methods of preparation and evaluation techniques of buccal and sub lingual drug delivery systems. Gastro retentitive drug delivery systems: Drug suitability, approaches and evaluation.

UNIT - VIII Controlled and sustained drug delivery systems: Concepts of design sustained release dosage forms, calculation of loading and maintenance doses based on zero order and first order release. Polymer Science: Types of polymers, properties of polymers, polymer solution and polymers in solid state, applications of polymers in pharmaceutical formulations

ANDHRA UNIVERSITY
TRANS-DISCIPLINARY RESEARCH HUB

MODEL QUESTION PAPER

Time: 3 hours
Max. Marks: 100

Answer any five questions

All questions carry equal marks

1. a) What are the objectives of bioequivalence studies? Explain the models used in bioavailability studies.

b) Write about the methods for improving bioavailability.

2. a) Write about model independent and model dependent methods for interpretation of dissolution Data.

b) Write about the theories of dissolution.

3.a) Write about the ingredients used in transdermal preparation.

b) Explain the evaluation methods for ophthalmic inserts.

4.a) Write about different types of coating techniques highlighting their relative merits.

b) Write the in process quality control tests for tablets with their limits of acceptance.

5. a) Explain the methods for studying drug-excipient compatibility.

b) What is stress testing and how it

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6. a) Write about different types of drug targeting

b) Write about the significance of liposomes and their methods of preparation.

7. a) Write about the theories of mucoadhesion

b) Mention the qualities of drugs suitable for designing gastroretentive drug delivery systems. Discuss about the techniques for preparation of effervescent gastric systems.

8. a) Explain the approaches for calculation of loading and maintenance dose with zero order release pattern.

b) Write about the hydrophilic polymers suitable for controlled drug delivery with suitable Examples.