

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES



*Affiliated To The Tamil Nadu Dr. MGR Medical University, Chennai
Approved by Pharmacy Council of India, New Delhi.*

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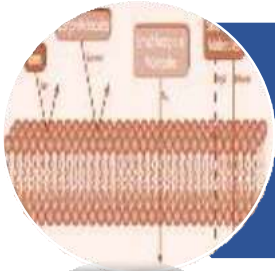
COURSE NAME : INDUSTRIAL PHARMACY I (BP 503 T)

V SEM / III YEAR

TOPIC 1 : PREFORMULATION STUDIES

SUB TOPIC: BCS Classification of Drugs & its Significant

BIOPHARMACEUTICAL CLASSIFICATION SYSTEM



A scientific framework for classifying drug substances based on their aqueous solubility and intestinal permeability



Established by Gordon Amidon et al.

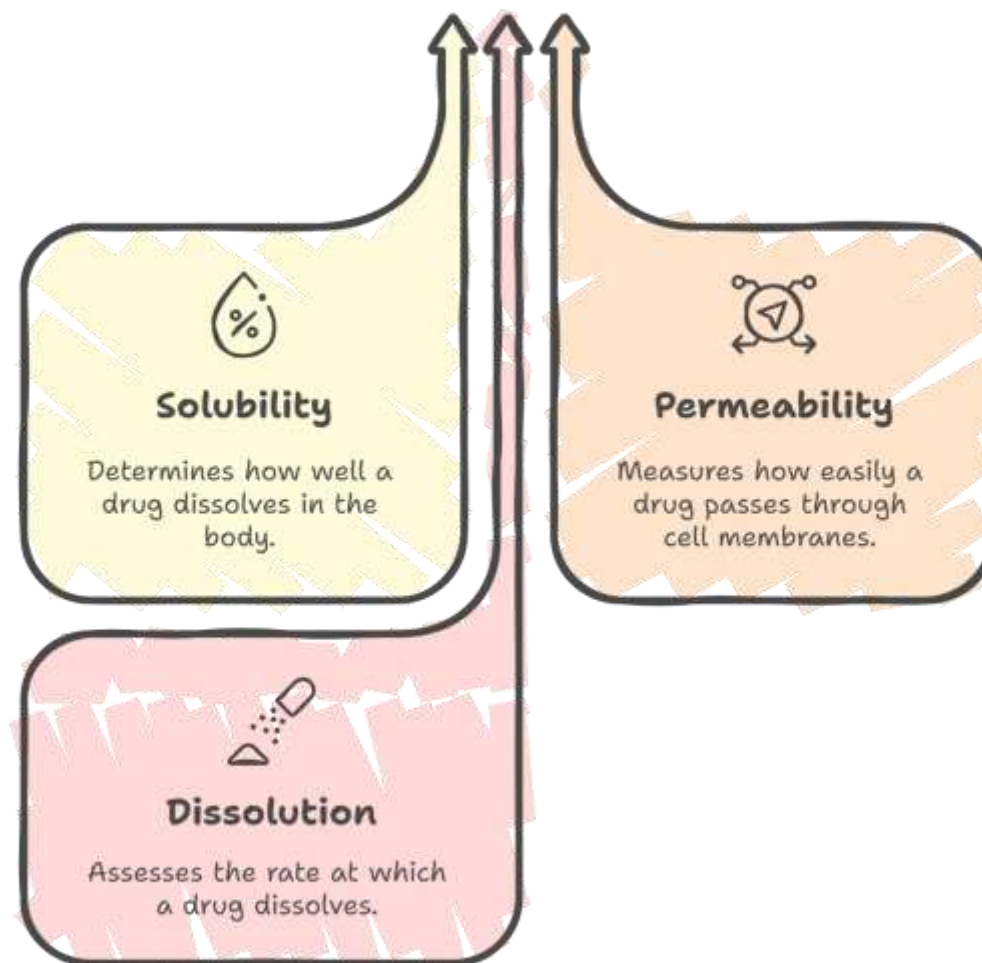


BCS has gained importance worldwide as a drug product regulation tool for scale-up and post- approval changes



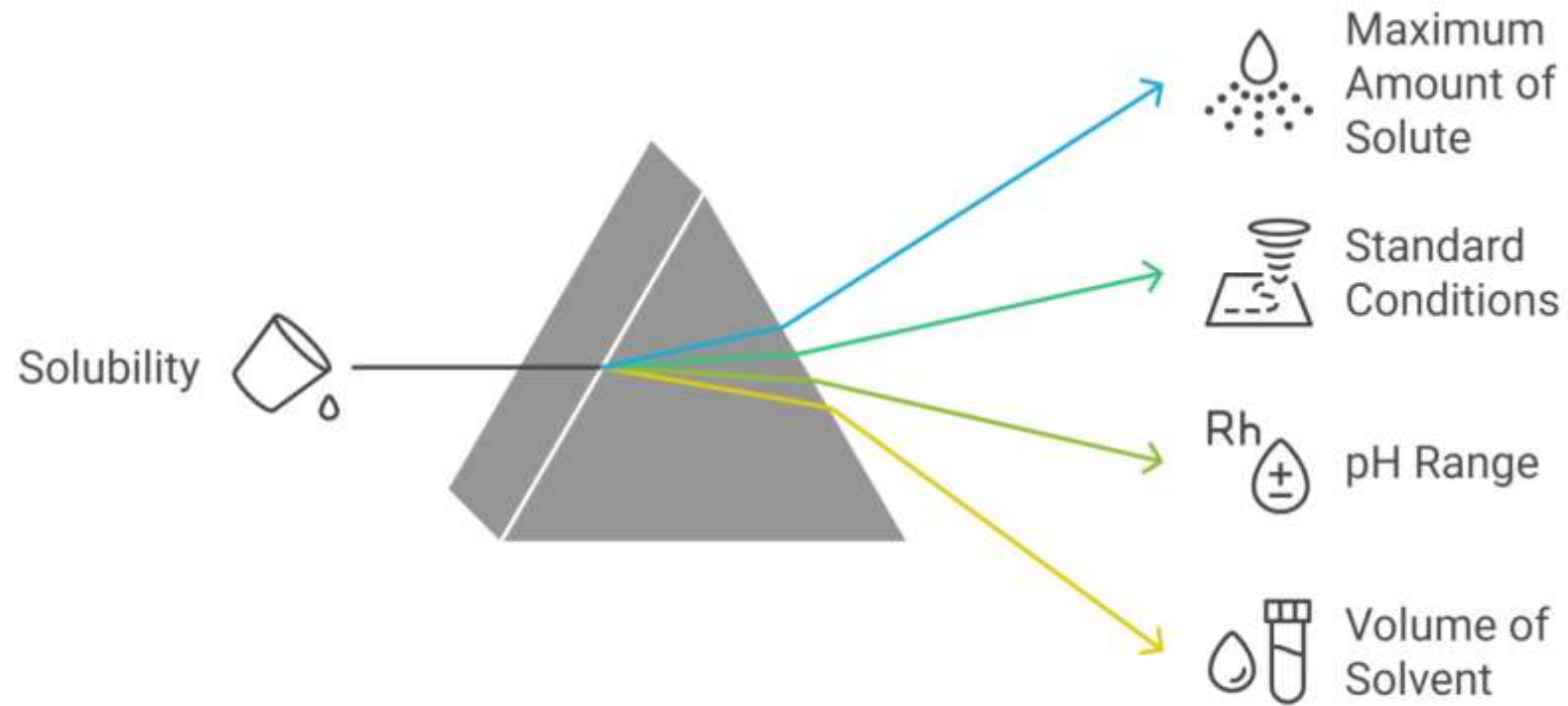
The aim of the BCS is to provide a regulatory tool for the replacement of certain BE studies by conducting accurate *in vitro* dissolution tests.

FACTOR AFFECTING ON BCS



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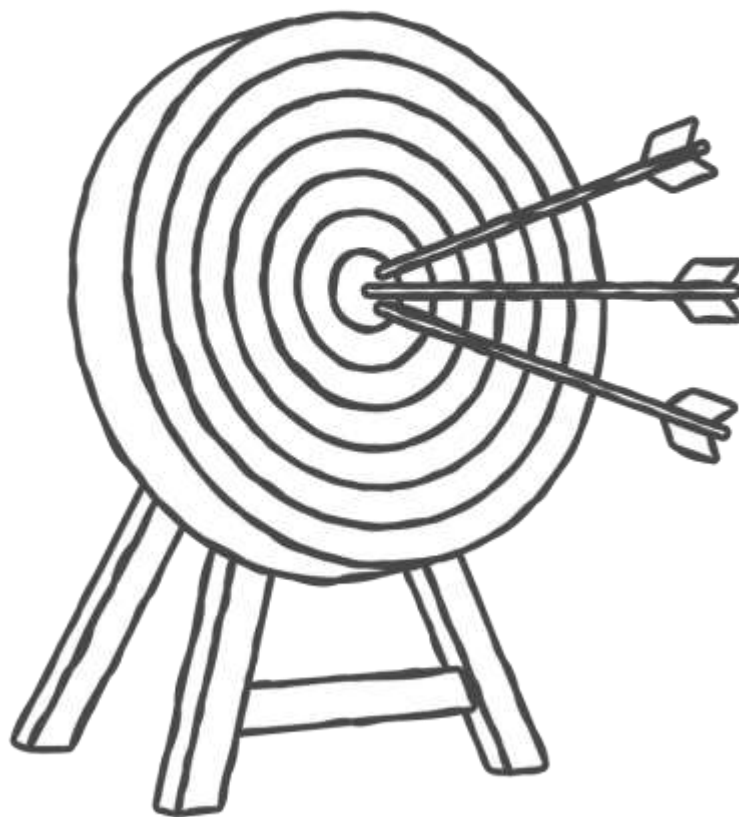
SOLUBILITY



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PERMEABILITY

Drug Permeability and Absorption



Drug Absorption

The ultimate goal of drug administration



Permeability

Ability to pass biological membranes



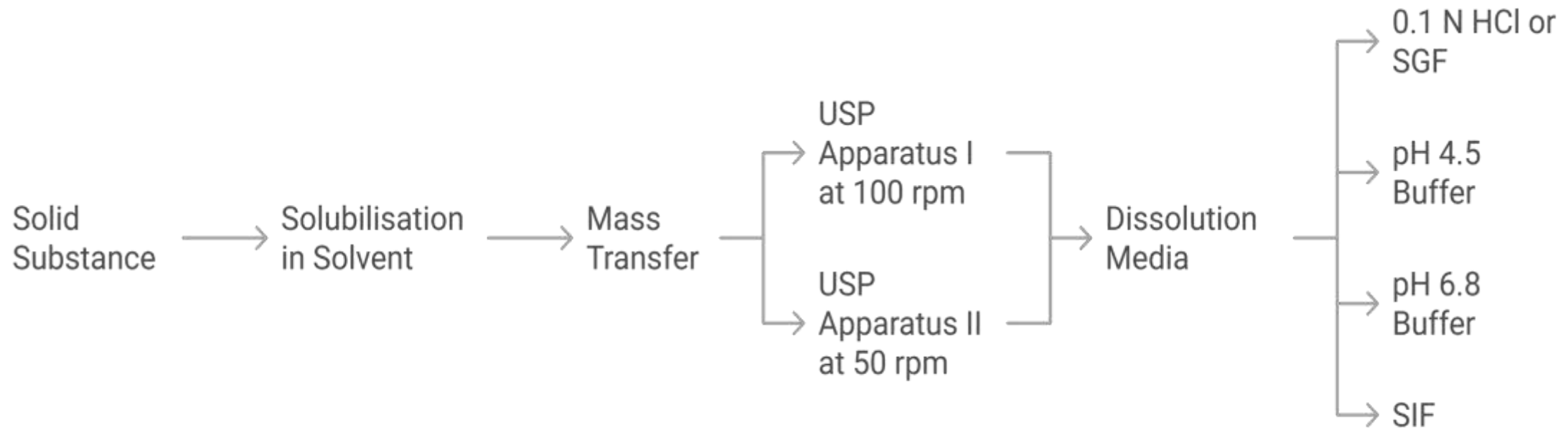
Lipophilicity

Affinity for lipid-rich environments

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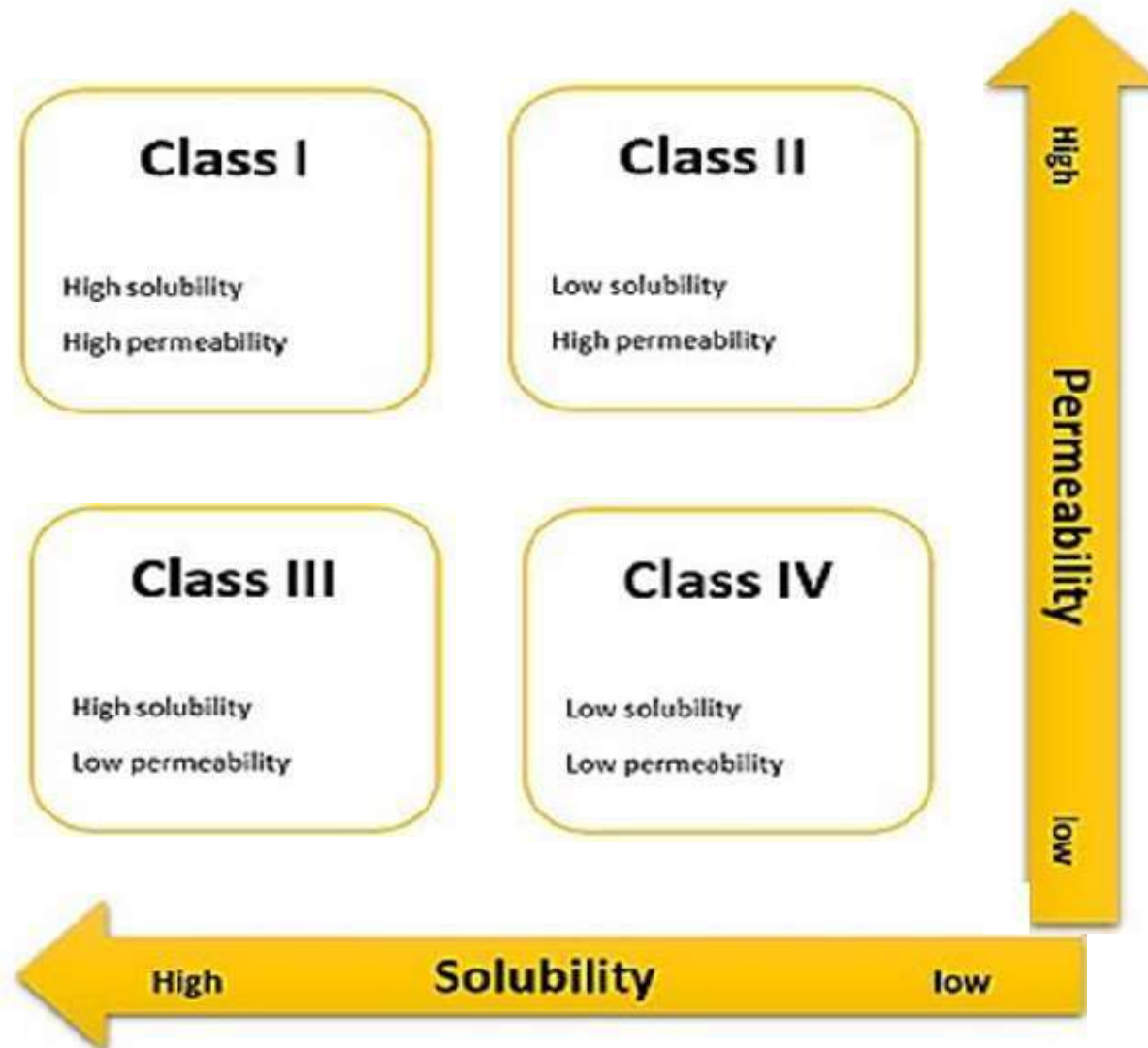
DISSOLUTION

Dissolution Process Flowchart



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BIOPHARMACEUTICAL CLASSIFICATION SYSTEM



CLASS I HIGH SOLUBILITY HIGH PERMEABILITY

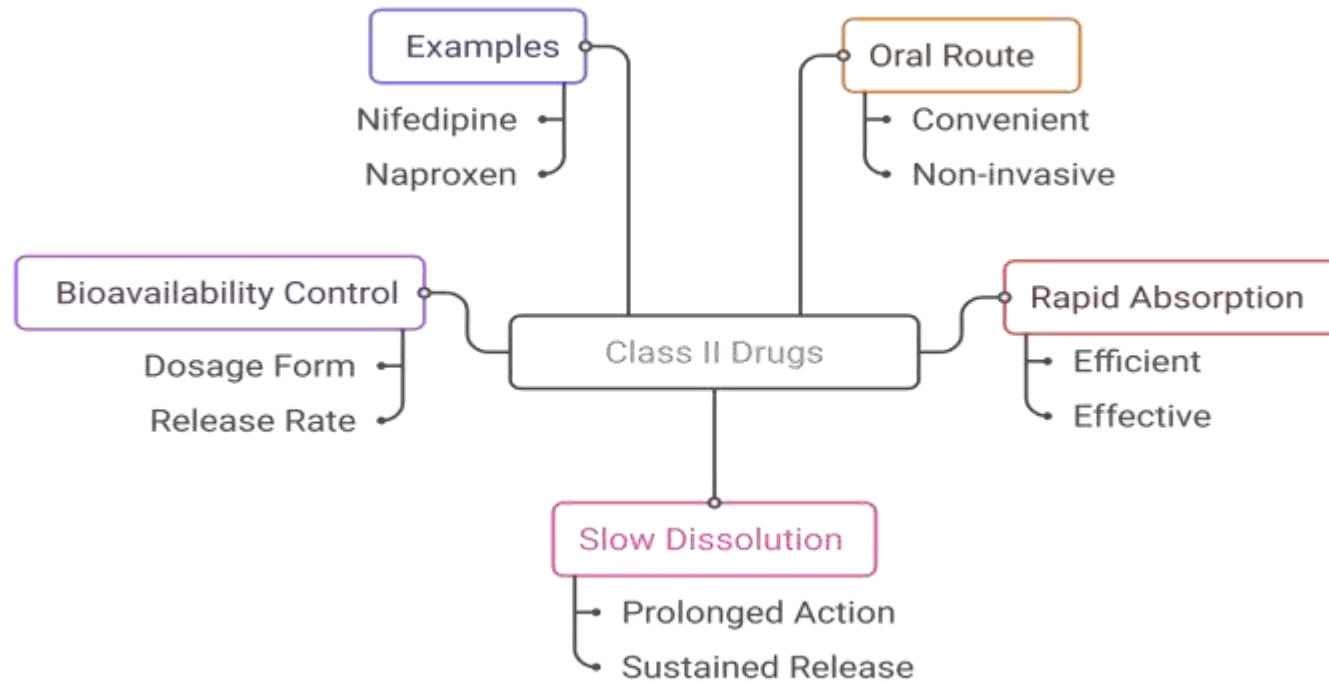
Class I Drug Characteristics



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CLASS II LOW SOLUBILITY HIGH PERMEABILITY

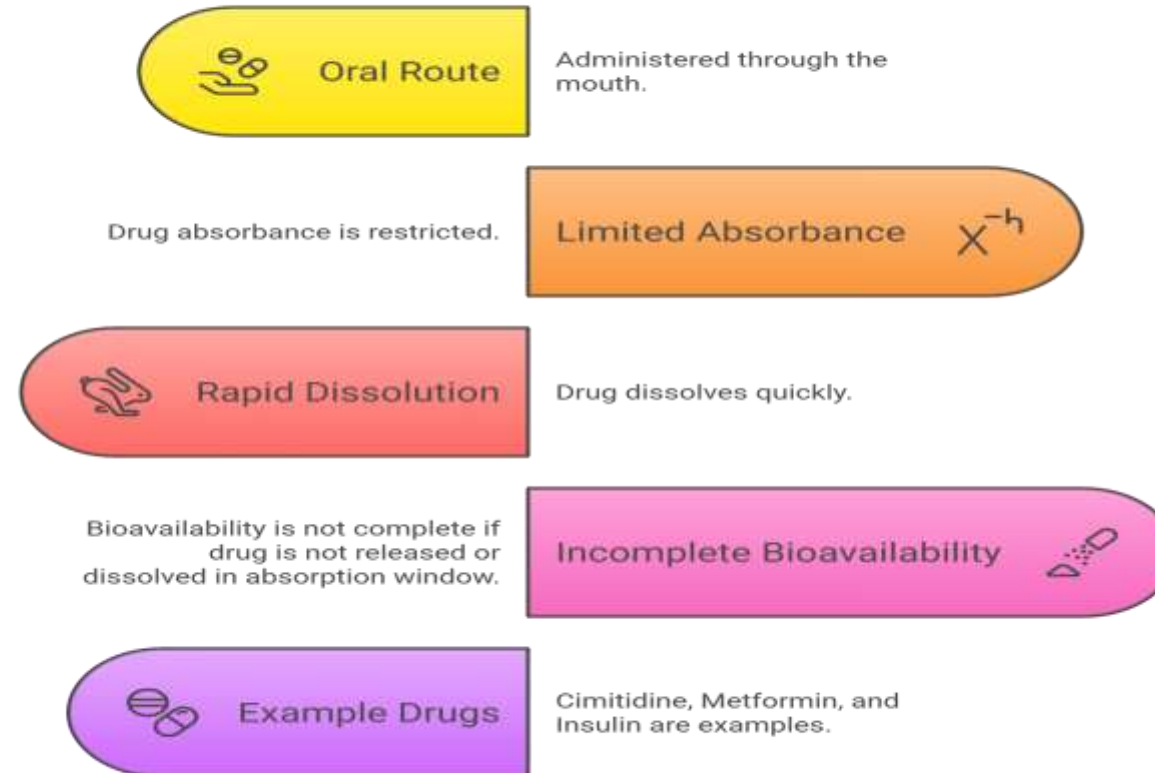
Class II Drugs: Characteristics and Examples



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CLASS III HIGH SOLUBILITY LOW PERMEABILITY

Class III Drug Characteristics



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CLASS IV - LOW SOLUBILITY LOW PERMEABILITY

Class IV Drug Absorption Challenges

Solubility Limitation

Prevents drug dissolution

Permeability Limitation

Blocks drug passage

Low Dissolution Rate

Slows drug absorption

Slow Therapeutic Action

Delays desired effects



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BCS CAN BE USED ASA KEY COMPONENT TO GUIDE DRUG DELIVERY SYSTEM DESIGN FOR ANY ROUTE OF ADMINISTRATION

BCS Class	Solubility	Permeability	Oral Dosage Form Approach	Chances of Non-oral Dosage Form being Required
1	High	High	Simple solid oral dosage form	
2	Low	High	• Techniques to increase surface area like particle size reduction, solid solution, solid dispersion • Solutions using solvents and/or surfactants	
3	High	Low	Incorporate permeability enhancers, maximize local luminal concentration	
4	Low	Low	Combine 2 and 3	

Biowaiver

What is a biowaiver?

It's an exemption from human bioequivalence studies when the active ingredients meet certain solubility and permeability criteria in vitro and the dissolution profile meets IR dosage form requirements.



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Criteria of Biowaiver

Same Excipients

The inactive ingredients should match those in the approved drug.



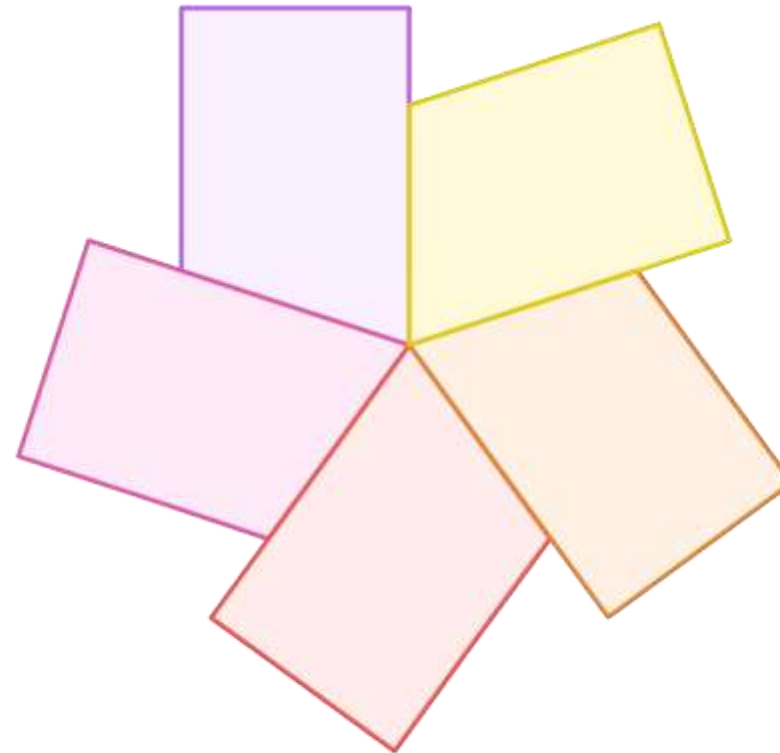
Wide Therapeutic Window

The drug should have a large difference between effective and toxic doses.



High Permeability

The drug should easily pass through biological membranes.



Rapid Dissolution

The drug should dissolve quickly and consistently.

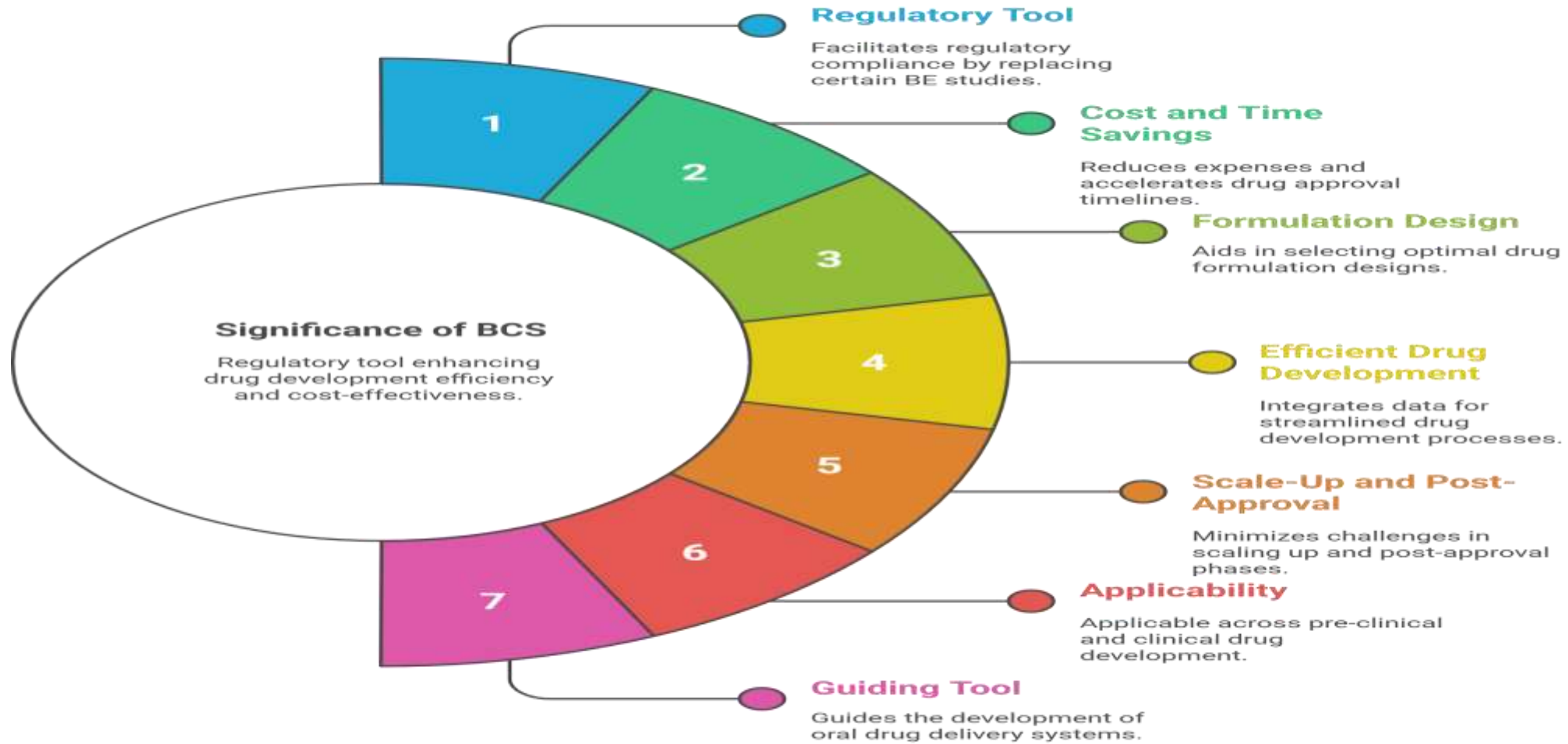


High Solubility

The drug should be highly soluble in water.

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SIGNIFICANCE OF BCS



ASSESSMENTS

1. What is the Biopharmaceutics Classification System (BCS)?



2.A drug has high solubility but low permeability. Into which BCS class does it fall, and what formulation strategies can improve its bioavailability?



3. How does particle size reduction affect the BCS class II drug's bioavailability?



4.How can prodrug formation help improve the permeability of BCS Class III drugs?

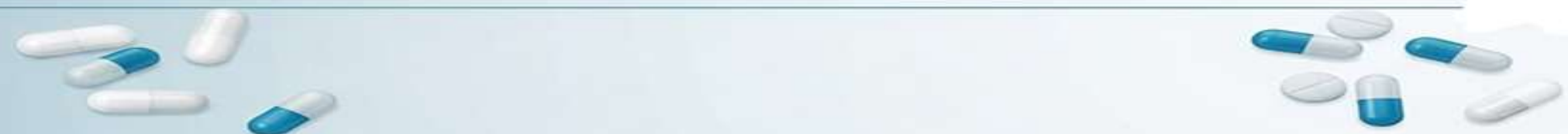


5. Compare the rate-limiting steps of absorption for BCS Class I and Class IV drugs.



REFERENCES

- ❖ Brahmankar, D. M and Jaiswal, Pharmacokinetics – A Treatise. 2 nd 29 and 332 - 335.
- ❖ Dr. Tipnis H.P. and Dr. Bajaj Amrita, Principles and applications of B 1st iopharmaceutics and Pharmacokinetics, edition 2002, reprint 2005, career publication, Page no. 332-340.
- ❖ Leon shargel, Susanna wu-pong, Andrew B.C.Yu , Applied Biopharmaceutics & Pharmacokinetics, 5 th edition 2005, published by the Mc Graw hills companies, page no. 431-436 & 482-484.



Thank You

