Biopharmaceutics Classification System (BCS)

- The Biopharmaceutics Classification System (BCS) is a scientific model that classifies drugs into four categories based on their solubility and intestinal permeability.
- It helps predict a drug’s absorption characteristics, guiding formulation design and regulatory decisions.

Purpose of BCS

- Supports drug development and bioequivalence studies.
- Helps determine eligibility for biowaivers (exemption from in vivo bioavailability studies).
- Assists in regulatory approvals and formulation strategies.

BCS Classification

Class	Solubility	Permeability	Examples
Class I	High	High	Paracetamol, Metoprolol
Class II	Low	High	Ibuprofen, Ketoprofen
Class III	High	Low	Cimetidine, Acyclovir
Class IV	Low	Low	Hydrochlorothiazide

Key Definitions

- **High Solubility**: Highest dose strength dissolves in ≤250 mL of water across pH 1–7.5.
- **High Permeability**: At least 90% of the administered dose is absorbed in humans.

Basic Concepts of Clinical Trials

What Are Clinical Trials?

- Clinical trials are systematic studies conducted on human subjects to evaluate the safety, efficacy, dosage, and side effects of new drugs or treatments.
- They are essential for regulatory approval and responsible drug development.

Phases of Clinical Trials

Phase	Objective	Participants	Key Focus
Phase I	Safety & dosage	20–100 healthy volunteers	Pharmacokinetics, tolerability

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Phase II	Efficacy & side effects	100–500 patients	Therapeutic effect and short-term safety
Phase III	Confirmation & comparison	1000–5000 patients	Efficacy vs. standard treatments
Phase IV	Post-marketing surveillance	General population	Long-term safety, rare or delayed effects

Regulatory Oversight

- In India, clinical trials are regulated by the New Drugs and Clinical Trials Rules, 2019, under the Central Drugs Standard Control Organization (CDSCO).

Ethical Requirements

- Informed consent from all participants
- Approval by an Institutional Ethics Committee (IEC)
- Compliance with Good Clinical Practice (GCP) guidelines

ANDA (Abbreviated New Drug Application)

What is ANDA?

- The Abbreviated New Drug Application (ANDA) is a submission made to the U.S. FDA to seek approval for a generic drug.

Key Features

- **No clinical trials required** – only bioequivalence studies are needed.
- The generic drug must be identical to the innovator product in:
    - Dosage form, strength, route of administration, quality, and performance characteristics.
- Lower development cost and faster approval compared to a New Drug Application (NDA).
- Intended to provide affordable alternatives to branded medicines without compromising efficacy or safety.

NDA (New Drug Application)

What is an NDA?

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- A New Drug Application (NDA) is a comprehensive document submitted to a drug regulatory authority—such as the U.S. Food and Drug Administration (US FDA) or the Central Drugs Standard Control Organization (CDSCO) in India—for approval to market a new pharmaceutical product.
- It serves as the final step in the drug development process, allowing the authority to evaluate whether the new drug is safe, effective, and of high quality for public use.

Purpose of an NDA

- To demonstrate the drug’s safety and efficacy based on scientific evidence.
- To provide detailed information on how the drug is manufactured, tested, stored, labeled, and packaged.
- To allow regulators to assess the overall risk-benefit profile before granting marketing approval.

Contents of an NDA

- **Preclinical data** (animal studies)
- **Clinical trial results** from **Phases I–III**
- Drug formulation details
- Manufacturing process and facility information
- Labeling and packaging specifications
- Safety, efficacy, and risk-benefit assessment

New Drug Development

- The development of a new drug is a long, complex, and highly regulated process involving multiple stages to ensure safety, efficacy, and quality before the drug reaches the market.

Stages of New Drug Development

1. Discovery and Preclinical Research

- Conducted in labs and animals (in vitro and in vivo testing)
- Evaluates toxicity, pharmacokinetics, and pharmacodynamics

2. Investigational New Drug (IND) Filing

- Submitted to regulatory authorities (e.g., **US FDA/CDSCO**)
- Seeks permission to start **human clinical trials**

3. Clinical Trials (Phases I–III)

- **Phase I**: Safety and dosage in healthy volunteers
- **Phase II**: Efficacy and side effects in a small patient group

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- **Phase III**: Large-scale testing for confirmation and comparison with existing treatments

4. **New Drug Application (NDA) Submission and Approval**
   - Comprehensive data submission for marketing authorization
5. **Post-Marketing Surveillance (Phase IV)**
   - Ongoing monitoring for long-term safety, rare adverse effects, and real-world effectiveness

Challenges in New Drug Development

- **Time-consuming**: Typically takes 10–15 years
- **Cost-intensive**: Involves millions to billions of dollars/rupees
- Requires strict regulatory compliance at every stage

New Drugs and Clinical Trials Rules, 2019 (India)

- Notified by the Ministry of Health and Family Welfare, these rules were introduced under the Drugs and Cosmetics Act, 1940 to streamline and regulate new drug approvals and clinical trials in India.

Objectives

- Ensure efficient, ethical, and transparent drug and trial approvals.
- Promote orphan drugs and innovative therapies.

Key Features

- **Expanded Definition of “New Drug”:** Covers new molecules, combinations, dosage modifications, and new indications.
- **Approval Timelines:**
  - **30 days** for Indian clinical trials
  - **90 days** for global/multinational trials
- **Registered Ethics Committees:** Must be registered with CDSCO and oversee trial approvals and participant safety.
- **Compensation & Medical Care:** Mandatory for trial-related injuries or deaths.
- **Trial Waivers:** Allowed in special cases (e.g., national emergency, serious disease, orphan drugs, prior foreign approval).
- **Fast-Track Approvals:** For orphan drugs, biologics, and drugs of national interest.
- **Clinical Trials Registry – India (CTRI):** All trials must be registered for transparency and monitoring.

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