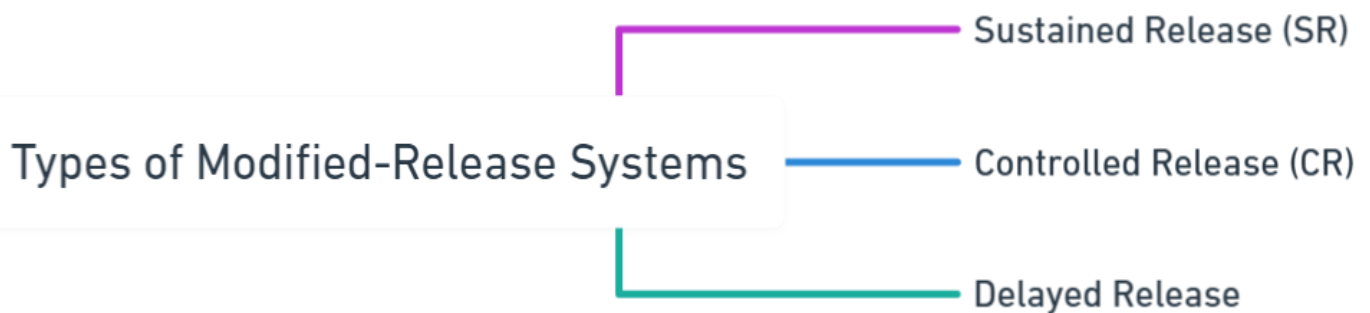


Application of Pharmacokinetics

Application of Pharmacokinetics in Modified-Release Drug Products

- **Modified-release (MR)** drug products are designed to release the drug in a controlled manner instead of releasing it immediately after administration.
- Pharmacokinetics plays a major role in designing these systems because it helps in understanding how drug concentration changes over time.

Types of Modified-Release Systems



1. Sustained Release (SR)

- Drug is released slowly over a long time
- Maintains drug levels within therapeutic range

2. Controlled Release (CR)

- Drug release is controlled at a constant rate

3. Delayed Release

- Drug release is delayed (e.g., enteric-coated tablets)

Role of Pharmacokinetics

Pharmacokinetics helps in:

1. Maintaining Steady Drug Levels

- Avoids peaks (toxicity) and troughs (ineffectiveness)

2. Reducing Dosing Frequency

- Improves patient compliance

3. Designing Release Rate

- Based on drug half-life and clearance

Important PK Considerations

1. Half-life ($t_{1/2}$)

- Drugs with short half-life are ideal for MR systems

2. Absorption Rate

- Should be slower than elimination rate

3. Therapeutic Window

- Narrow window requires precise control

Design considerations

- Drug solubility
- Stability
- Absorption window (site in GI tract where drug is absorbed)
- Dose size

Advantages

- Reduced side effects
- Improved patient compliance
- Stable plasma concentration

Limitations

- Dose dumping risk
- Not suitable for all drugs
- Complex formulation

Application of Pharmacokinetics in Targeted Drug Delivery Systems

- Targeted drug delivery systems are designed to deliver drugs specifically to a particular site in the body (e.g., tumor cells) instead of distributing throughout the body.

Why targeting is needed

- Reduce side effects
- Increase drug concentration at target site
- Improve therapeutic effectiveness

Types of Targeting

1. Passive Targeting

- Drug accumulates naturally (e.g., tumors via leaky vessels)

2. Active Targeting

- Drug is attached to ligands that bind specific receptors

PK Considerations

1. Distribution

- Must ensure drug reaches target tissue

2. Clearance

- Drug should not be eliminated before reaching target

3. Half-life

- Longer circulation time improves targeting

Key factors

1. Particle size

- Affects circulation and tissue penetration

2. Surface properties

- Charge and hydrophilicity affect distribution

3. Circulation time

- Longer circulation improves targeting

Carriers Used

- Liposomes
- Nanoparticles
- Monoclonal antibodies

Benefits

- Increased efficacy
- Reduced toxicity
- Lower dose required

Challenges

- Complex design
- Stability issues
- Immune system recognition

Application of Pharmacokinetics in Biotechnological Products

- Biotechnological drugs are complex molecules such as proteins, peptides, and antibodies.
- Their pharmacokinetics is very different from small chemical drugs.

Key differences from conventional drugs

- Large molecular size
- Poor oral absorption
- Usually given by injection
- Complex distribution and elimination

Pharmacokinetic behavior

1. Absorption

- Usually slow after subcutaneous or intramuscular injection
- Oral route not suitable (degraded in GI tract)

2. Distribution

- Limited due to large size
- Mostly remain in plasma or extracellular fluid

3. Metabolism

- Broken down into amino acids
- Not metabolized by liver enzymes like CYP450

4. Elimination

- Through cellular uptake and degradation
- Kidney filtration for smaller proteins

Important concepts

- **Target-mediated drug disposition (TMDD)**
 - Drug binds to specific receptors, affecting its distribution and elimination
- **Immunogenicity**
 - Immune response against the drug can alter its pharmacokinetics

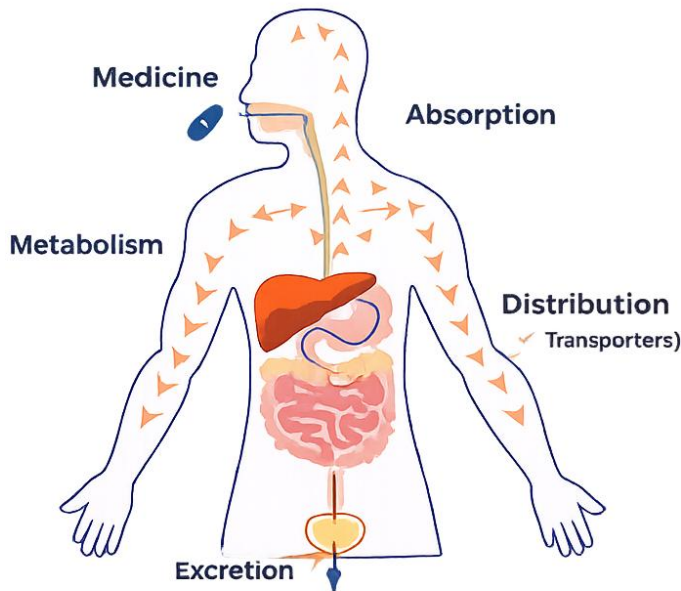
Applications

- Dose optimization
- Designing dosing intervals
- Improving drug stability

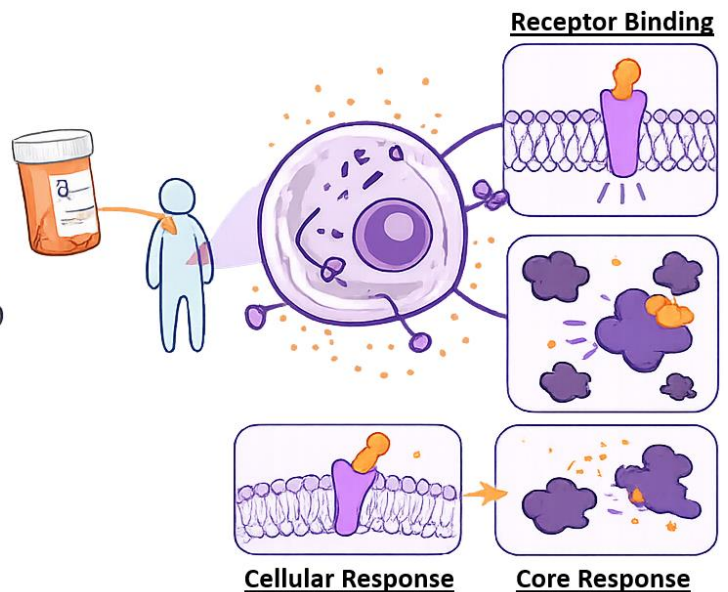
Introduction to Pharmacokinetics and Pharmacodynamics, Drug Interactions

- Pharmacokinetics (PK) and pharmacodynamics (PD) are closely related but describe different aspects of drug action.

Pharmacokinetics



Pharmacodynamics



Pharmacokinetics (PK)

- What the body does to the drug
- Includes absorption, distribution, metabolism, excretion

Pharmacodynamics (PD)

- What the drug does to the body
- Includes mechanism of action and effect

Relationship Between PK and PD

- PK determines drug concentration
- PD determines effect based on that concentration

Drug Interactions Overview

- Drug interactions can affect both PK and PD.

PK Interactions

- Affect drug concentration
- Example:**



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