Product Stability

Degradation Kinetics

- Degradation kinetics studies **how fast a drug degrades over time** and how this degradation depends on different conditions like temperature, pH, and light.

What is degradation

- Degradation means chemical breakdown of a drug
- **Leads to:**
  - Loss of potency
  - Formation of impurities
  - Reduced safety and effectiveness

Purpose of studying degradation kinetics

- To predict shelf life
- To understand stability
- To design proper storage conditions

Order of reaction in degradation

Drug degradation usually follows specific reaction orders.

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1. Zero-order kinetics

Concept

- Drug degrades at a **constant rate**
- Same amount is lost per unit time

Equation

$$C = C_0 - kt$$

- **Where:**
  - C= concentration at time t
  - C_0= initial concentration
  - k= rate constant

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Graph

- Straight line when **concentration vs time** is plotted

Examples

- Some suspensions
- Controlled release systems

2. First-order kinetics

Concept

- Degradation rate depends on **drug concentration**
- Higher concentration → faster degradation

Characteristics

- Rate decreases over time
- Most drugs follow this order

Equation

$$\log C = \log C_0 - \frac{kt}{2.303}$$

Graph

- Straight line when **log concentration vs time** is plotted

3. Second-order kinetics

- Less common
- Depends on concentration of two reactants

Rate Constant (k)

- Indicates the speed of degradation
- Higher k→ faster degradation

Half-Life (t½)

- Time required for **50% drug degradation**
- **For first-order kinetics:**

$$t_{1/2} = \frac{0.693}{k}$$

Shelf Life (t_{90})

- Time for 10% degradation (90% drug remains)
- **For first-order kinetics:**

$$t_{90} = \frac{0.105}{k}$$

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Effect of Temperature (Arrhenius Equation)

$$k = Ae^{-E_a/RT}$$

- **Where:**
  - E_a= Activation energy
  - T= Temperature (in Kelvin)
  - R= Gas constant
  - A= Frequency factor

Importance of Arrhenius Equation

- Predicts stability at different temperatures
- Used in accelerated stability studies

Overall Importance

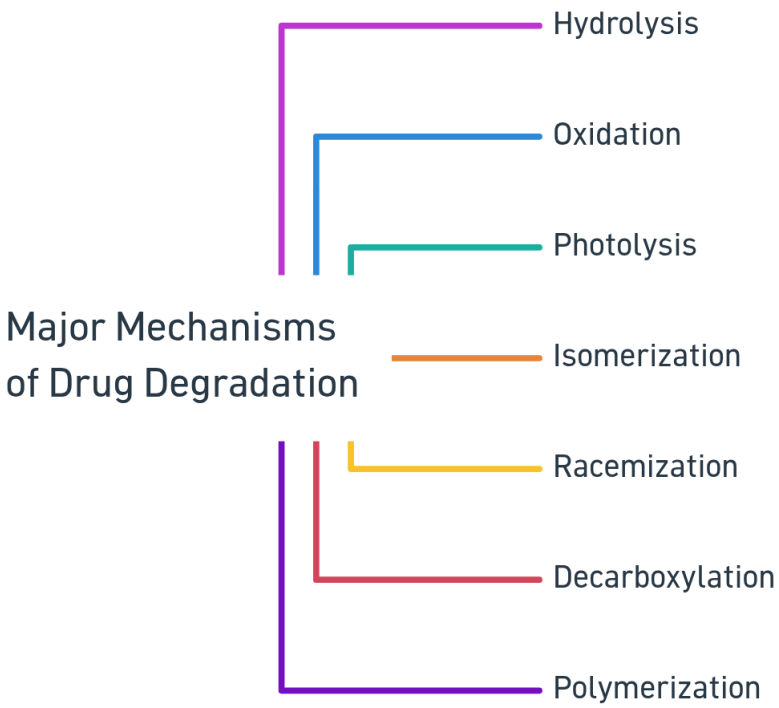
- Helps in predicting drug stability and shelf life
- Guides storage and packaging conditions
- Essential for regulatory approval
- Supports quality assurance

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Mechanisms of Drug Degradation

- **Drug degradation** mechanisms explain how and why drugs undergo chemical or physical breakdown under various conditions.

Major Mechanisms of Drug Degradation



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1. Hydrolysis

Definition

- Chemical reaction of drug with **water**

Common in

- Esters
- Amides

Example

- Aspirin hydrolyzes into salicylic acid

Factors Affecting Hydrolysis

- pH
- Temperature
- Moisture

2. Oxidation

Definition

- Reaction of drug with **oxygen**

Common in

- Drugs with double bonds
- Phenols

Examples

- Adrenaline
- Vitamin C

Indicators

- Color change
- Formation of impurities

Accelerated by

- Light
- Heat
- Metal ions

Prevention

- Use of **antioxidants** (e.g., ascorbic acid)
- Airtight containers

3. Photolysis

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Definition

- Degradation due to **light exposure (UV/visible light)**

Sensitive Drugs

- Riboflavin
- Nifedipine

Prevention

- Amber-colored bottles
- Light-resistant packaging

4. Isomerization

Definition

- Conversion of drug into a different isomer

Effect

- Reduced pharmacological activity

5. Racemization

Definition

- Conversion of an active enantiomer into a less active or inactive form

Effect

- Decrease in drug effectiveness

6. Decarboxylation

Definition

- Removal of **carbon dioxide (CO_2)** from the molecule

Effect

- Structural change leading to degradation

7. Polymerization

Definition

- Combination of small drug molecules to form **larger molecules (polymers)**

Effect

- Loss of drug activity
- Possible change in physical properties

Importance of Studying Degradation Mechanisms

- Helps in selecting stabilizers (antioxidants, buffers)

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