

Sustained Release(SR) and Controlled Release (CR) formulations

Introduction to Sustained Release (SR) and Controlled Release (CR) Formulations

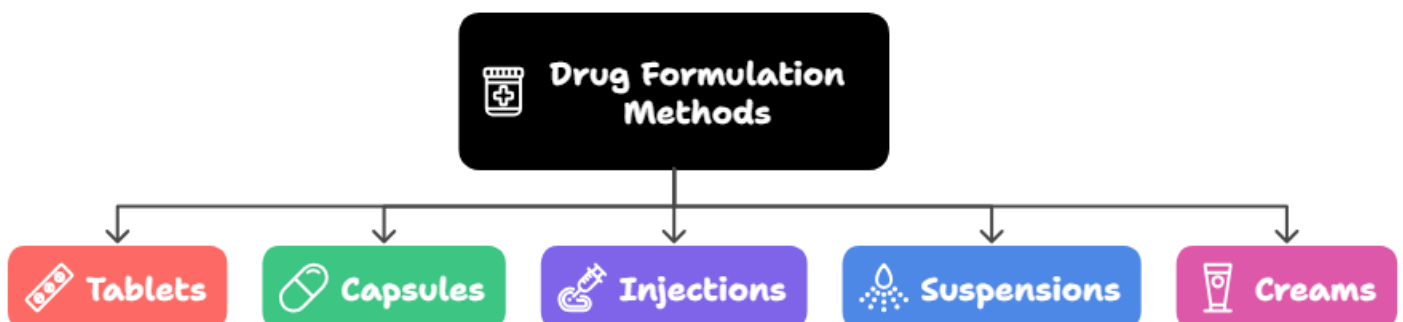
What are Drug Formulations?

- Drug **formulation** is the final medicinal product prepared by combining the **active drug** with other substances (called **excipients**) so that it can be safely and effectively delivered into the body.

Drug Formulations



- Drugs can be formulated as:
 - Tablets
 - Capsules
 - Injections
 - Suspensions
 - Creams



Immediate Release (IR) Formulations

Immediate Release



- Many traditional medicines are immediate release (IR) formulations.
- **In these formulations:**
 - The drug is released quickly after administration.
 - This leads to rapid absorption into the bloodstream.

Need for Modified Release Systems

- Some drugs need to stay in the body for a long period and maintain a stable concentration.
- To achieve this, special formulations called modified release systems are developed.
- **Two important types of modified release systems are:**
 - Sustained Release (SR)
 - Controlled Release (CR)
- **These systems control the:**
 - Rate of drug release
 - Time of drug release
 - Location of drug release in the body

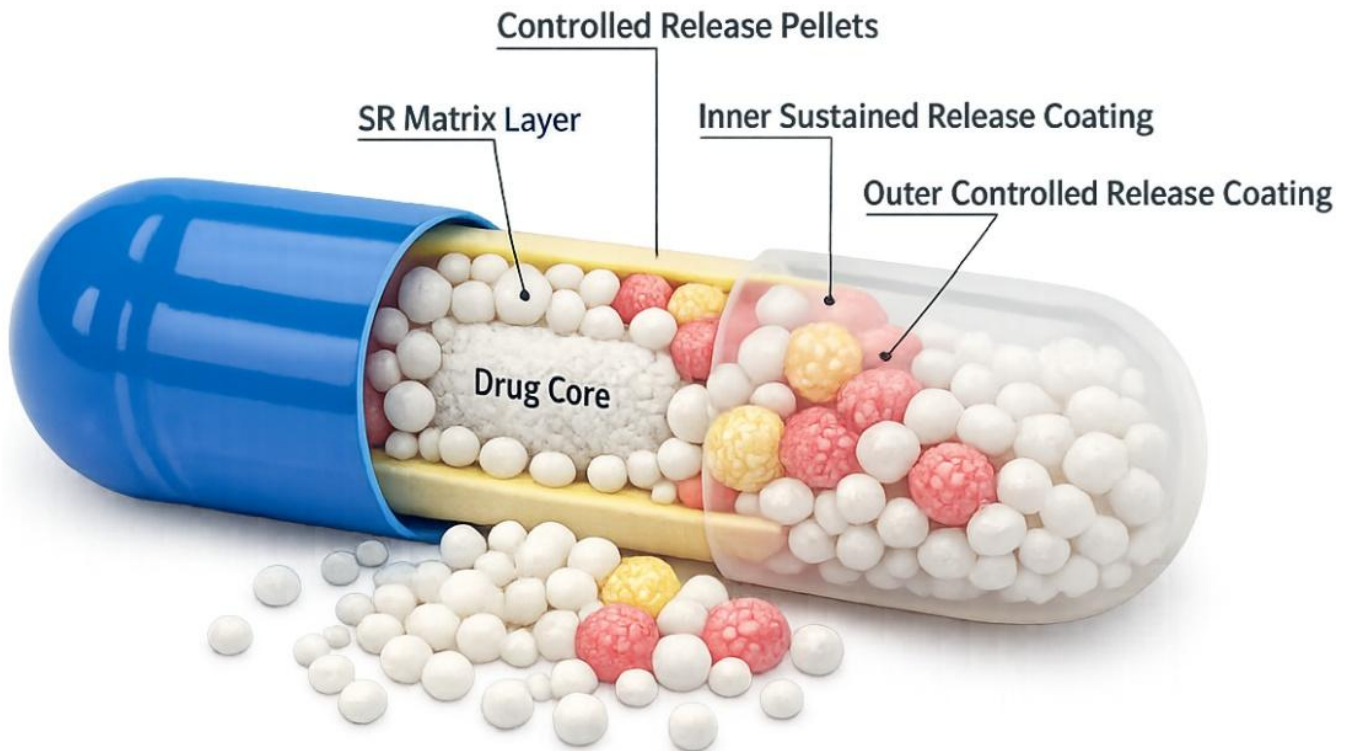
Sustained Release (SR) Formulations

Definition

- Sustained Release formulations are dosage forms designed to release a drug slowly over an extended period of time after administration.
- The main purpose is to maintain therapeutic drug levels in the body for a longer duration compared with conventional dosage forms.

- **In SR systems:**

- Drug release rate is slower than immediate release
- But not necessarily constant



Key Idea

- Instead of releasing the entire drug immediately, the formulation releases the drug gradually so that the drug remains in the body longer.

Example

- A tablet designed to release drug slowly over 12 hours instead of releasing all the drug immediately.

Important Characteristics

- Slower drug release rate
- Prolonged therapeutic effect
- Reduced dosing frequency
- Drug concentration may still fluctuate, but less than conventional dosage forms

Basic Concept

- When a drug is taken normally:
 - Drug dissolves rapidly
 - Blood concentration rises quickly
 - After some time the drug is eliminated
 - Concentration falls below therapeutic level

- This creates peaks and valleys in plasma drug concentration.

Aim of SR Formulations

- **SR formulations aim to:**
 - Reduce rapid peaks
 - Maintain drug levels for longer
 - Reduce fluctuations in blood concentration

Controlled Release (CR) Formulations

Definition

- Controlled Release formulations are dosage forms that release the drug at a predetermined, controlled rate for a specific period of time.
- The goal is to maintain a constant drug concentration in the bloodstream for a longer time.

Key Idea

- Drug release is controlled so that the same amount of drug is released per unit time.

Characteristics

- Predictable release rate
- Constant plasma drug concentration
- Reduced fluctuations in blood drug levels
- Often designed for once-daily dosing

Examples

- Some once-daily tablets used for:
 - Hypertension
 - Diabetes
 - Pain management
- are controlled release formulations.

Difference Between SR and CR

Feature	Sustained Release	Controlled Release
Drug release rate	Slow but not constant	Precisely controlled and constant
Plasma concentration	Reduced fluctuations	Almost constant concentration

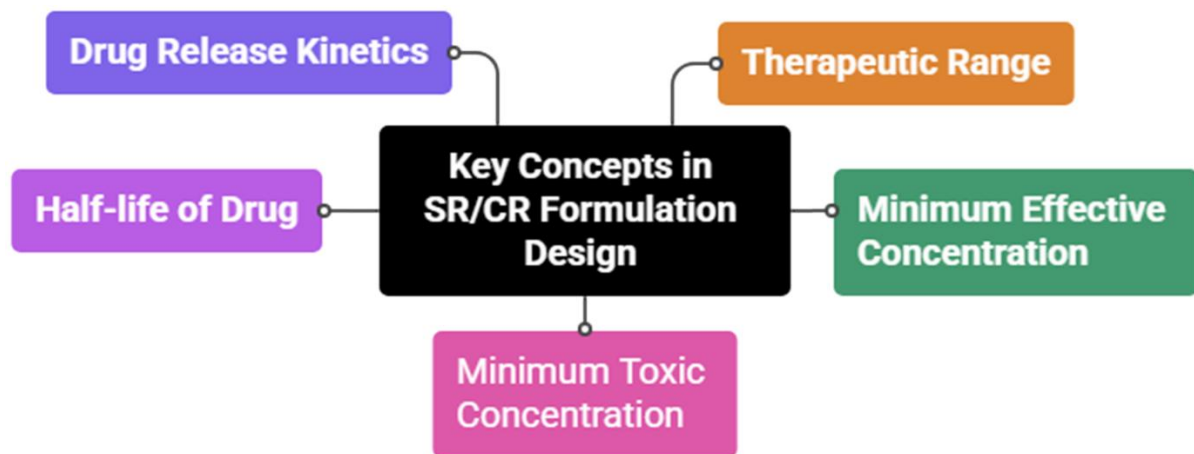
Complexity	Moderate	High
Predictability	Lower	Higher

Important Concept

- All controlled release formulations are sustained release systems.
- But not all sustained release systems are controlled release systems.

Basic Concepts of SR/CR Drug Delivery Systems

Important concepts are involved in designing SR/CR formulations



1. Therapeutic Range

- The therapeutic range is the concentration range where a drug is effective without causing toxicity.
- **Drug levels:**
 - Below this level → **drug ineffective**
 - Above this level → **drug toxic**
- SR/CR systems aim to maintain drug concentration within this range for long periods.

2. Minimum Effective Concentration (MEC)

- The minimum effective concentration is the lowest concentration of a drug required to produce a therapeutic effect.
- If drug levels fall below MEC, the drug will not work.

3. Minimum Toxic Concentration (MTC)

- The minimum toxic concentration is the drug concentration above which toxic effects start to appear.
- The safe therapeutic range lies between MEC and MTC.



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