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SUSTAINED-RELEASE DOSAGE FORMS: PRINCIPLES, TECHNOLOGIES AND THERAPEUTIC SIGNIFICANCE

Abhishek Raj*[1], Dr. Amit Sharma[2]

[1]PhD Scholar (Department of Pharmacy) Faculty of Medical, Paramedical and Allied Health Sciences, Jagannath University, Jaipur, Rajasthan, India.
[2]Dean (Medical, Paramedical and Allied Health Sciences) and HOD (Pharmacy), Jagannath University, Jaipur, Rajasthan, India.

***Corresponding Author: Abhishek Raj**

PhD Scholar (Department of Pharmacy) Faculty of Medical, Paramedical and Allied Health Sciences, Jagannath University, Jaipur, Rajasthan, India. **DOI:** https://doi.org/10.5281/zenodo.20019689

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Abstract
Sustained-release (SR) dosage forms are pharmaceutical formulations designed to release a drug at a predetermined rate in order to maintain a constant drug concentration in systemic circulation for a prolonged period. These systems reduce dosing frequency, improve patient compliance, and maintain therapeutic drug levels while minimizing fluctuations associated with conventional dosage forms. This article discusses the principles, mechanisms, formulation approaches, advantages, limitations, and current advancements in sustained-release drug delivery systems.

KEYWORDS: Sustained Release, SRDF, Matrix System, Modified Release, Extended Release.

INTRODUCTION

Conventional dosage forms typically release the active pharmaceutical ingredient (API) rapidly after administration, leading to sharp peaks and troughs in plasma drug concentration. Such fluctuations may result in sub-therapeutic levels or increased risk of toxicity. Sustained-release dosage forms were developed to overcome these limitations by delivering drugs gradually over an extended period.

Sustained-release systems fall under the broader category of modified-release drug delivery systems and are particularly useful for drugs with short biological half-lives, narrow therapeutic windows, or those requiring long-term therapy in chronic conditions such as hypertension, diabetes, and cardiovascular diseases.

Concept of Sustained-Release Drug Delivery

A sustained-release dosage form is designed to release the drug slowly and continuously so that therapeutic levels are maintained for an extended duration after a single administration.

The objectives of sustained-release formulations include

- Maintaining therapeutic plasma concentration for longer periods
- Reducing dosing frequency
- Minimizing side effects associated with peak plasma levels
- Improving patient adherence to therapy
- Enhancing drug utilization efficiency

Unlike immediate-release formulations, SR systems control the drug release rate through formulation design and material properties.

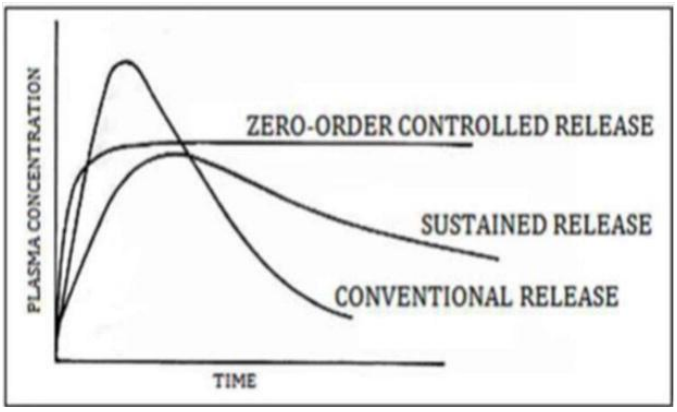

Figure 1. Plasma drug concentration vs. time profile.

Mechanisms of Drug Release

Drug release from sustained-release systems occurs through several mechanisms depending on the design of the formulation.

- **Diffusion-Controlled Release:** Drug molecules diffuse through a polymeric membrane or matrix into the surrounding biological fluids. The rate of diffusion depends on the concentration gradient and the permeability of the polymer barrier.
- **Erosion-Controlled Release:** Drug release occurs as the matrix material gradually erodes or degrades in biological fluids.

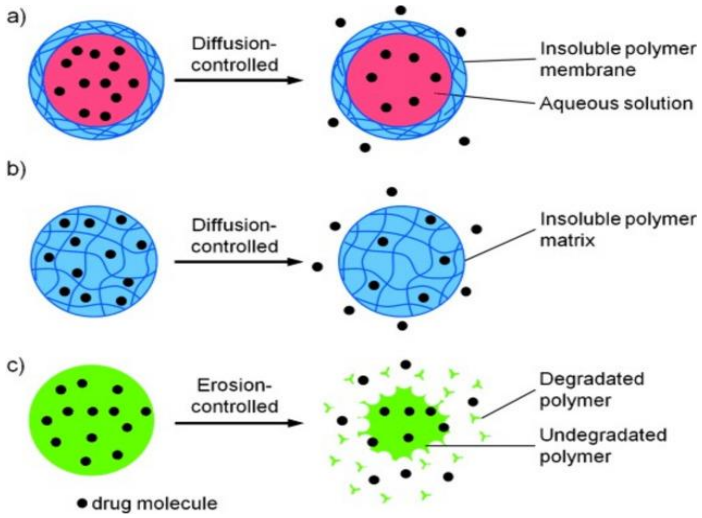

Figure 2. Diffusion-controlled and Erosion-controlled release.

- **Dissolution-Controlled Release:** In this mechanism, the drug or its coating dissolves slowly in gastrointestinal fluids, thereby controlling the release rate.

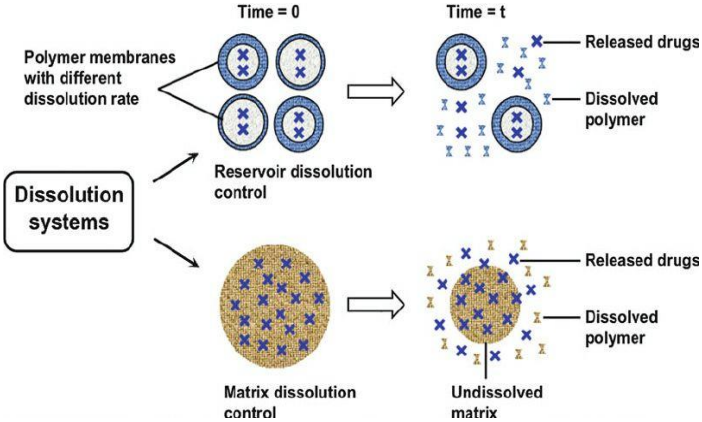

Figure 3. Dissolution-controlled release.

- **Osmotically-Controlled Release:** Osmotic pressure drives the release of the drug through a semi-permeable membrane. Water enters the dosage form, dissolves the drug, and the solution is pumped out through a small orifice

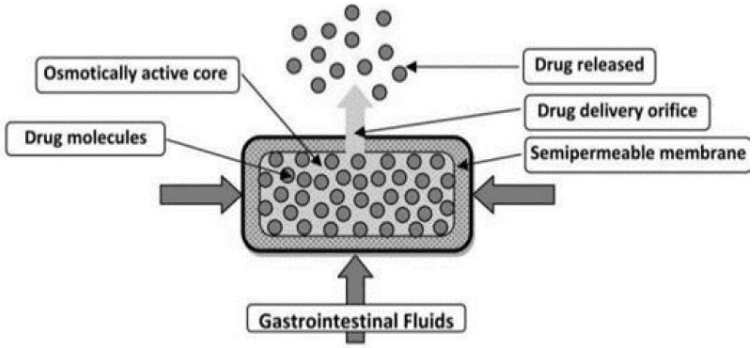

Figure 4. Osmotically-controlled release.

Types of Sustained-Release Dosage Forms

1. Matrix Systems: The drug is uniformly dispersed within a polymeric matrix. Drug release occurs through diffusion or matrix erosion. Examples include:

- Hydrophilic matrices (e.g., hydroxypropyl methylcellulose)
- Hydrophobic matrices (e.g., waxes, ethylcellulose)

2. Reservoir Systems: The drug core is surrounded by a polymeric membrane that controls drug diffusion.

Example: Coated Tablets.

3. Osmotic Pump Systems: These systems utilize osmotic pressure to release drugs at a controlled rate, largely independent of gastrointestinal pH and motility. Example: OROS (Osmotic-controlled release oral delivery system) tablets.

4. Multiparticulate Systems: Drug is incorporated into pellets, beads, or microspheres which are filled into capsules or compressed into tablets to achieve controlled release. Example: Capsule filled pellets.

Selection Criteria for Drugs Suitable for Sustained Release:

Not all drugs are ideal candidates for sustained-release formulations. Suitable drugs generally possess the following characteristics:

- Moderate half-life (2–8 hours)
- High therapeutic index
- Adequate solubility and permeability
- Dose size less than 500 mg
- Stable in gastrointestinal fluids

Drugs with very short or extremely long half-lives, narrow absorption windows, or poor solubility are generally unsuitable.

Polymers used in Sustained Release Formulations

Table 1: Polymers used in Sustained release formulations.

S. No.	Polymer	Type	Function
1.	Hydroxypropyl methylcellulose (HPMC)	Hydrophilic	Matrix former
2.	Ethylcellulose	Hydrophobic	Rate controlling membrane
3.	Carbopol	Hydrophilic	Gel forming polymer
4.	Eudragit RS/RL	Synthetic Polymer	Controlled Permeability
5.	Poly lactic-co-glycolic acid (PLGA)	Biodegradable	Sustained drug release

Advantages of Sustained-Release Dosage Forms

Sustained-release drug delivery systems offer several therapeutic and pharmacoeconomic benefits:

- Reduced dosing frequency
- Improved patient compliance
- Reduced fluctuation in plasma drug levels
- Decreased side effects and toxicity
- Enhanced therapeutic efficiency
- Reduced total drug consumption in some cases

These benefits make SR systems particularly useful in the treatment of chronic diseases.

Limitations of Sustained-Release Systems

Despite their advantages, sustained-release formulations have certain limitations:

- Risk of dose dumping if the system fails
- Higher cost of formulation and manufacturing
- Difficulty in dose adjustment once administered
- Not suitable for drugs requiring rapid onset of action
- Possible accumulation in case of impaired drug elimination.

Evaluation Parameters of Sustained Release Tablets

Table 2: Evaluation parameters of sustained release tablets.

S. No.	Parameters	Purpose
1.	Dissolution	Determines drug release profile
2.	Hardness	Tablet mechanical strength
3.	Friability	Resistance to abrasion
4.	Drug Content Uniformity	Ensures dose accuracy
5.	Swelling Index	Indicates polymer hydration

Recent Advances in Sustained-Release Technology

Recent developments in pharmaceutical technology have significantly improved sustained-release systems. Advances include:

- Nanoparticle-based drug delivery systems
- Biodegradable polymer matrices
- Smart polymers responsive to pH, temperature, or enzymes
- 3D-printed controlled release tablets
- Targeted sustained-release formulations for specific tissues

These innovations are expanding the application of sustained-release formulations in personalized medicine and advanced therapeutic strategies.

CONCLUSION

Sustained-release dosage forms represent a significant advancement in drug delivery technology. By controlling the release rate of drugs, these systems maintain therapeutic drug levels for extended periods, improve patient adherence, and enhance treatment outcomes. Ongoing research in materials science, nanotechnology, and pharmaceutical engineering continues to refine sustained-release systems, offering promising prospects for more efficient and patient-friendly drug therapies.

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