ISSN: 0976-7126
Dubey *et al.*, 17(6):17-23, 2026

International Journal of Pharmacy & Life Sciences
Open Access to Researcher

Controlled Release Drug Delivery Systems: Recent Trends and Innovations

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Article info

Received: 11/04/2026

Revised: 29/05/2026

Accepted: 10/06/2026

www.ijplsjournal.com

Abstract

A controlled drug delivery system administers medication locally or systemically at a predetermined pace and for a specified duration, ensuring that oral medications are continuously delivered throughout the gastrointestinal tract (GIT) at known, repeatable kinetics. By utilizing drug-encapsulating devices, these advanced systems enable the regulated release of therapeutic agents over extended periods ranging from days to months. Consequently, this approach offers numerous significant advantages over conventional drug administration techniques, including the ability to precisely customize drug release rates, safeguard chemically delicate medications from premature degradation, and substantially improve overall patient comfort and compliance.

Keywords: Controlled drug delivery System (CDDS), Novel drug delivery System (NDDS), Polymers, Phytosomes, Liposomes, Nanoparticles, Niosomes, Nanoemulsions, Bioavailability.

Introduction

Maintaining drug levels within a desired range, requiring fewer administrations, making the best use of the medication in question, and improving patient compliance are all examples of controlled drug delivery systems. The potential drawbacks, such as the potential toxicity or non-biocompatibility of the materials used, unwanted byproducts of degradation, any surgery needed to implant or remove the system, the possibility of patient discomfort from the delivery device, and the higher cost of controlled-release systems compared with conventional pharmaceutical formulations, cannot be disregarded despite the potential benefits. The optimal drug delivery system should be biocompatible, inert, mechanically robust, patient-friendly, and able to achieve high drug loading. safe from unintentional release, straightforward to make and sterilize, and simple to administer and remove. Achieving a delivery profile that would result in a high blood level of the medication over an extended period of time was the aim of many of the initial controlled-release devices. When using conventional medication delivery methods, the drug's level in the blood rises with each dosage before falling until the subsequent one. The crucial aspect of traditional medication administration is that the agent's blood level should stay between a minimum value, below which the medicine loses its effectiveness, and a maximum value, which may indicate a dangerous level.

Polymer Used in Control Drug Delivery System: In the realm of medication delivery, polymers are becoming more and more significant. Polymers are used in a variety of pharmaceutical applications, such as binders in tablets and agents that control viscosity and flow in liquids, suspensions, and emulsions. Polymers can be applied as film coatings to change a medicine's release characteristics, improve drug stability, and mask an undesirable taste.

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The importance of pharmaceutical polymers for applications involving controlled drug distribution is the main topic of the review. Today, sixty million patients receive safer and more effective amounts of the medications they require to combat a range of human illnesses, including cancer, thanks to sophisticated drug delivery systems. When a medicine or other active agent is carefully mixed with a polymer-natural or synthetic-so that the active agent is released from the material in a predetermined way, this is known as controlled drug delivery, or CDD. The active agent may be released continuously over an extended period of time, cyclically over an extended period of time, or in response to external events or the environment. In any event, the goal of regulating drug administration is to obtain more successful treatments while removing the possibility of both underdosing and overdose.

Control Release Dosage Form: The modified-release (MR) dosage form is defined by the United States Pharmacopoeia (USP) as "the one for which the drug release characteristics of time course and/or location are chosen to accomplish therapeutic or convenience objectives not offered by conventional dosage forms such as solutions, ointments, or promptly dissolving dosage forms." An extended-release (ER) dosage form is one type of MR dosage form that permits at least a two-fold decrease in dose frequency or a notable improvement in patient compliance. performance in comparison to that offered as a traditional dose form (a prompt drug-releasing dosage form or a solution). "Controlled release (CR), prolonged release, sustained or slow release (SR), and long-acting (LA)" have all been used interchangeably with "extended release."

Nearly all of the currently marketed monolithic oral ER dosage forms fall into one of the following two technologies:

1. Hydrophilic, hydrophobic or inert matrix systems: These consist of a rate controlling polymer matrix through which the drug is dissolved or dispersed.
2. Reservoir (coated) systems where drug containing core is enclosed within a polymer coating. Depending on the polymer used, two types of reservoir systems are considered.

(a) Simple diffusion/erosion systems where a drug-containing core is enclosed within hydrophilic and/or water-insoluble polymer coatings. Drug release is achieved by diffusion of the drug through the coating or after the erosion of the polymer coating.

(b) Osmotic systems where the drug core is contained within a semi-permeable polymer membrane with a mechanical/laser drilled hole for drug delivery. Drug release is achieved by osmotic pressure generated within the tablet core.[1]

Clinical Advantages [2],[3]

- Reduction in frequency of drug administration
- Improved patient compliance
- Reduction in drug level fluctuation in blood
- Reduction in total drug usage when compared with conventional therapy
- Reduction in drug accumulation with chronic therapy
- Reduction in (local/systemic)
- Stabilization of drug medical toxicity condition (because of more uniform drug levels)
- Improvement in bioavailability of some drugs because of spatial control
- Economical to the health care providers and the patient

Potential Limitations

- Delay in onset of drug action
- Possibility of dose dumping in the case of a poor formulation strategy
- Increased potential for first pass metabolism
- Greater dependence on GI residence time of dosage form
- Possibility of less accurate dose adjustment in some cases
- Cost per unit dose is higher when compared with conventional doses
- Not all drugs are suitable for formulating into ER dosage form

Recent Developments in Controlled Drug Delivery System

Phytosome**,** Liposome**,** Nanoparticles, Nanoemulsions, Niosomes [4]

ISSN: 0976-7126
Dubey *et al.*, 17(6):17-23, 2026

Phytosome: Phytosomes, a drug delivery system predominantly based on phospholipids, have been found to be promising for natural drug delivery [5]. Phytosomes are a novel natural drug delivery method that results from complexing polyphenolic phytoconstituents within the molar ratio with phosphatidyl choline [6]. Because the phytosome provides an envelope-like coating over the drug's active ingredient, the natural extract's main ingredient is protected from bacterial and digestive secretion destruction. Phytosomes can accurately absorb from a water-loving environment into a lipid-loving environment of the cell membrane, ultimately leading to blood circulation [7]. It has enhanced bioavailability and can be utilized to treat a number of deadly diseases without denaturing the active phytocompounds. Phytosomes exhibit superior therapeutic and pharmacokinetic characteristics compared to traditional herbal extract.

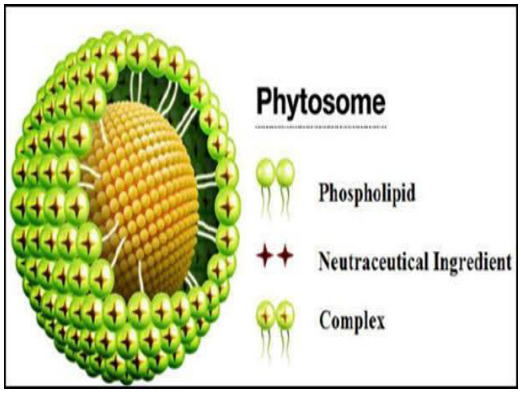

Fig 1: Phytosomes

Advantages of Phytosomes

- It improves the oral and topical absorption of lipid insoluble polar phytoconstituents, demonstrating better bioavailability and, thus, much greater therapeutic efficacy.
- Significant drug entrapment.
- The active ingredient's dose required decreases as its absorption improves.
- Although phosphatidylcholine is used to prepare phytosomes, it also functions as a hepatoprotective, providing a synergistic effect when hepatoprotective materials are used.
- Because phosphatidylcholine molecules and phytoconstituents create chemical interactions, Phytosomes exhibit a better stability profile [8],[9].

Liposomes: A liposome is a structure made up of one or more concentric spheres of lipid bilayers divided by aqueous buffer or water compartments. Naturally occurring bilayers are primarily composed of phospholipids. Phosphatidylcholines (PC), phosphatidylethanolamines (PE), and phosphatidylserines (PS) are examples of these phospholipids [10]. Liposomes are made up of tiny phospholipid vesicles that enclose an aqueous area with a diameter of between 0.03 and 10 µm. composed of aqueous compartments surrounded by one or more concentric spheres of lipid bilayers. Due to their ability to transport both hydrophilic and lipophilic molecules, liposomes have been gaining popularity as a drug delivery mechanism [11]. The pharmaceutical and cosmetic industries make extensive use of liposomes as carriers for various compounds. Furthermore, the food and agricultural industries have extensively researched the use of liposome encapsulation to create delivery systems.

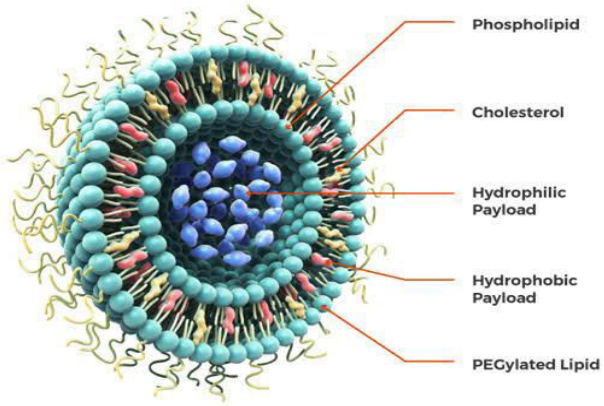

Fig.2 Liposomes

Advantages of Liposomes [14],[15],[16]

- Encapsulate every medicinal molecule, both lipophilic and hydrophilic.
- Strong solubilization ability.
- Show outstanding organic, chemical, and colloidal stability.
- Reduce their absorption through macrophages.
- Improving the encapsulated drug's therapeutic efficacy.
- Keep the bloodstream at a therapeutic medication level.

ISSN: 0976-7126
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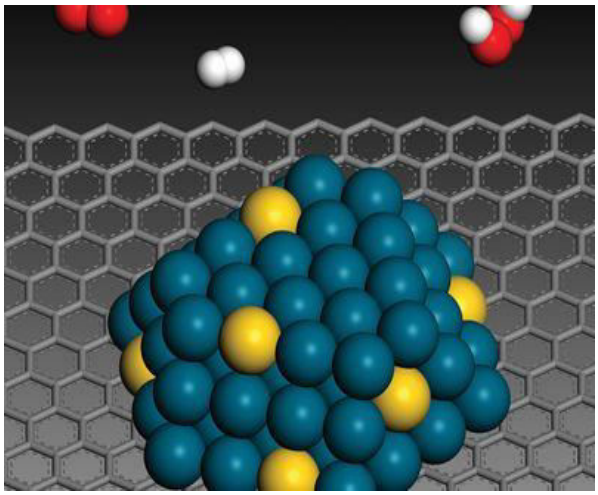
- Ensure medicine safety from environmental influences.
- Encourage medication molecules to be delivered intracellularly.

Nanoparticle: Particulate dispersions or solid particles with a length between 10 and 1000 nm are referred to as nanoparticles. the medication was either dissolved, trapped, encapsulated, or attached to the matrix of nanoparticles. Within the solid state, nanoparticles can be either amorphous or crystalline and are made up of nanospheres and nanocapsules with sizes ranging from 10 to 200 nm. Nanoparticle preparation has made extensive use of polymeric materials. Nanoparticles, nanospheres, or nanocapsules may be produced, depending on the preparation technique. While nanospheres are matrix systems, nanocapsules are systems in which the medication is contained within a hollow space encased in a totally distinct polymer membrane. wherein the medication is evenly and physically distributed. These days, biodegradable polymeric nanoparticles-especially those coated in hydrophilic polymers like poly (ethylene glycol) (PEG), known as long-circulating debris-have been utilized as potential drug delivery [17],[18].

Fig 3: Nanoparticle

Advantages of nanoparticles

- They can be stored for at least a year and



are non-toxic, biodegradable, and site-specific.
- They offer controlled drug release rates and particle degradation properties that can be easily adjusted by choosing different matrix components [19].
- They offer standard pharmacological response/unit dose and increased therapeutic efficacy.
- Drug/protein balance will be improved by nanoparticles against enzymatic breakdown [20].
- By affixing specified ligands to the surface of particles, they can target a medicine to a specific location within the body.
- Excessive drug loading and the possibility of drug integration into systems without any chemical reaction are critical issues for maintaining drug activity [21].

Niosomes: Similar to liposomes, niosomes have a multilameller vesicular shape and are made of non-ionic surfactants instead of phospholipids, which are liposome additives [22],[23]. Niosomes, also known as non-ionic surfactant vesicles, are currently being thoroughly researched as a potential tool for liposomes. Different types of surfactants were reported to create vesicles with the ability to trap and retain hydrophilic and hydrophobic solute particles [24],[25] Fig. No. 04 structure of noisome.

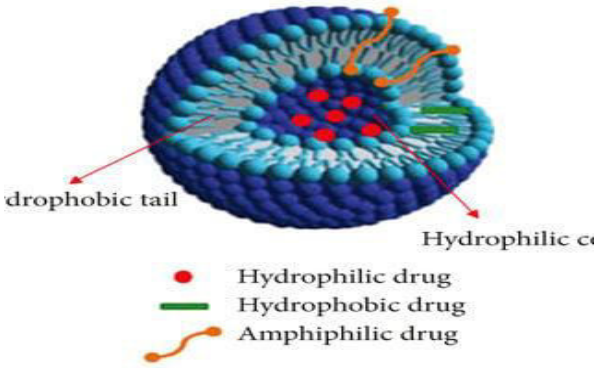


Fig 4: Niosomes

Advantages of Niosomes

- Compared to traditional oily formulations, niosomes have a greater therapeutic benefit and better patient compliance.
- Because niosomes can entrap hydrophilic, lipophilic, and amphiphilic medicines, they can be used in the delivery of a wide variety of medications [26].

- Niosomes exhibit controlled and prolonged drug release due to depot formation.
- The drug's niosome size, shape, content, and fluidity can be regulated as needed.
- Compared to traditional dose formulations, niosomes have greater absorption.
- Niosomes were effectively used to deliver concentrated medications to various organs.
- Compared to liposomes, niosomes are more stable [27].
- Niosomes can improve medication penetration via the skin [28].

Nano-emulsions: Drug molecules can be found in nano-emulsions, a colloidal particulate system with submicron sizes. They range in size from 10 to 1,000 nm. These suppliers are stable spheres having an amorphous, lipophilic, negatively charged surface. It is possible to improve site specificity by using magnetic nanoparticles. As a drug delivery system, they improve the medication's therapeutic efficacy while reducing side effects and toxic reactions. Reticuloendothelial system (RES) infection treatment, hepatic enzyme replacement therapy, cancer treatment, and vaccine are among the main uses [29]. Generally speaking, emulsions-also referred to as macroemulsions-are immiscible phases scattered within another [30].

Advantages of Nano-emulsion

- Offers aqueous dose forms for medications that are insoluble in water.
- Removes absorption variability [31].
- Boosts bioavailability.
- They don't exhibit the problems caused by sedimentation, flocculation, creaming, and coalescence.
- Boost the absorption rate [32].

Conclusion

A Novel Drug Delivery System (NDDS) represents a paradigm shift in pharmaceutical science, combining advanced delivery techniques with innovative formulations to surpass the limitations of conventional dosage forms. Unlike traditional therapeutics, which often suffer from poor bioavailability, frequent dosing, and systemic side effects, NDDS focuses on optimizing the pharmacokinetic and pharmacodynamic profiles of active ingredients. The primary advantage of an NDDS lies in its ability to provide the optimum drug dose at the proper location and the best time within the body. By achieving spatial and temporal control over drug release, these systems maximize therapeutic efficacy while minimizing toxic side effects in non-target tissues. From an economic perspective, NDDS allows for the highly efficient use of expensive active pharmaceutical ingredients (APIs) and specialized excipients, resulting in an overall discount in manufacturing costs and healthcare expenditures. Furthermore, these systems offer unparalleled utility to patients by dramatically improving clinical aid and therapeutic outcomes. By reducing dosing frequency-such as transforming a thrice-daily oral regimen into a once-weekly transdermal patch or a targeted nanoparticle injection-NDDS vastly improves patient comfort and compliance. Ultimately, by shifting the focus from simply administering a drug to precisely managing its journey through the biological system, Novel Drug Delivery Systems enhance the patient's overall standard of living and provide a sophisticated, patient-centric approach to modern healthcare.

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Cite this article as:
Dubey K. K., Dubey A. and Darwhekar G. N. (2026). Controlled Release Drug Delivery Systems: Recent Trends and Innovations. *Int. J. of Pharm. & Life Sci.,* 17(6):17-23.

Source of Support: Nil
Conflict of Interest: Not declared
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