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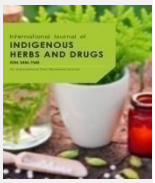

EMERGING CONTROLLED DRUG DELIVERY TECHNOLOGIES: A COMPREHENSIVE REVIEW

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ABSTRACT

Controlled drug delivery systems (CDDS) represent an advanced approach to pharmacotherapy aimed at maintaining drug plasma concentrations within the therapeutic range for prolonged periods. By releasing drugs at a predetermined rate and site, these systems minimize fluctuations associated with conventional dosage forms, thereby reducing dosing frequency, adverse effects, and improving patient compliance. This review summarizes the principles, mechanisms, and types of controlled and sustained-release drug delivery systems, with emphasis on oral controlled release formulations. Various approaches including diffusion-controlled, dissolution-controlled, osmotic, and biodegradable polymer-based systems are discussed, along with materials commonly employed in formulation design. The advantages of CDDS such as improved bioavailability, predictable pharmacokinetics, targeted delivery, and enhanced therapeutic efficacy are highlighted, while limitations including formulation complexity, dose dumping risk, and variability due to gastrointestinal physiology are also addressed. Recent technological advancements ranging from macro- to nano-scale delivery systems, including microencapsulation and targeted delivery strategies, are reviewed. The clinical relevance of CDDS in reducing dosing frequency and maintaining uniform plasma drug levels for local or systemic action is emphasized. Finally, current challenges and future perspectives in the development of controlled drug delivery systems are outlined, underscoring their significant role in optimizing drug therapy and improving overall treatment outcomes globally today.

Keywords: *plasma drug concentration, Polymer-based delivery systems, drug concentration, Polymer-based delivery system.*

1. INTRODUCTION

Desired drug levels are among the advantages of controlled medication delivery systems. They may have drawbacks, though, including toxicity, unwanted byproducts, surgery, discomfort for patients, and possible adverse effects. The drawbacks of traditional drug administration systems, which frequently include fast drug absorption and clearance, resulting in fluctuating plasma drug levels, gave rise to the idea of controlled drug delivery. Unwanted side effects or less than ideal therapeutic outcomes may arise from this. On the other hand, controlled drug delivery systems, or CDDS, are made to release medications at a set pace, increasing patient compliance, safety, and efficacy. By avoiding side effects linked to peak medication concentrations, decreasing dosage frequency, and maintaining constant plasma drug concentrations, CDDS can maximize drug therapy [1]. As a result of tighter blood level management, this could improve product safety and lessen the severity and frequency of serious adverse medication reactions [2]. Controlled drug distribution systems are essential for increasing therapeutic efficacy while lowering adverse effects. They make it possible to precisely regulate when and how a medication is released into the body, guaranteeing that the proper quantity reaches the goal. Certain sophisticated systems make use of intelligent materials that, in response to certain triggers, such as variations in pH or temperature, may release drugs [3]. In the past, alkaline compounds or buffers have been included in solid oral formulations of several acidic drugs that undergo dissolution rate-limited absorption [4]. Drugs can be administered through various routes; however, of all the routes of administration, the oral route of administration is the most convenient for administering and for dosage adjustments [5]. The ideal polymer balances swelling,

erosion, and dissolution processes. However, achieving high gel-state viscosity and maintaining a constant gel layer for linear drug release over prolonged periods remains a challenge due to various dynamic phases in polymer relaxation, disentanglement, and erosion [6]. Controlled-release drug delivery systems maintain plasma concentration within the therapeutic range, minimizing side effects and administration frequency by providing uniform drug concentration to the absorption site [7].

History

The development of drug delivery systems dates back to the early 20th century, with the introduction of injectable drug formulations for parenteral administration. However, It's fascinating to observe the evolution of Delivery of drugs within the past 60 years, transitioning from the first generation's emphasis on oral and transdermal formulations with controlled release technologies to the second generation's focus on advanced systems like zero-order release and environment sensitive delivery using smart polymers and hydrogels. The progress reflects a dynamic field adapting to emerging technologies and scientific advancements [8].

1) CONTROLLED DRUG DELIVERY SYSTEM

In recent years, considerable attention has been focused on the development of new drug delivery systems. There are a number of reasons for the intense interest in new systems. First, recognition of the possibility of repeatenting successful drugs by applying the concepts and techniques of controlled release drug delivery systems, coupled with the increasing expense in bringing new drug entities to market, has encouraged the development of new drug delivery systems. Second, new systems are needed to deliver the novel, genetically engineered pharmaceuticals, i.e., peptides and proteins, to their site of action without incurring significant immunogenicity or biological inactivation. Third, treating enzyme deficient diseases and cancer therapies can be improved by better targeting. The USP defines modified-release forms as those that use drug-release characteristics to achieve therapeutic or convenience not offered by conventional dosage forms [9]. These systems involve simple diffusion/erosion systems or osmotic systems, where the drug core is enclosed within a polymer membrane [10].

2) RELEASE MECHANISMS

Diffusion-Controlled Systems

These are the most commonly used systems, where the drug diffuses through a polymer matrix or membrane. The release rate depends on the drug's solubility, the polymer's permeability, and the thickness of the matrix. Erosion-Controlled Systems: In these systems, drug release is governed by the erosion or degradation of the polymer matrix [11].

Osmotic Systems

These systems use osmotic pressure to drive drug release. A drug is typically housed in a semi-permeable membrane that allows water to enter, dissolving the drug and forcing it out through a small hole in the membrane at a constant rate.

3) FACTORS INFLUENCING THE DESIGN AND PERFORMANCE OF CDDS

To establish criteria for the design of controlled release products, a number of variables must be considered.

1. Drug properties

The physicochemical properties of a drug, including stability, solubility, partitioning characteristics, charge and protein binding property play a dominant role in the design and performance of controlled release systems.

2. Route of drug delivery

The area of the body in which drugs will be applied or administered can be restrictive on the basis of technological achievement of a suitable controlled release mechanism or device.

3. Target sites

In order to minimize unwanted side effects, it is desirable to maximize the fraction of applied dose reaching the target organ or tissue [12].

4.The disease

Pathological changes during the course of a disease can play a significant role in the design of a suitable drug delivery system.

5. The patient

Whether the patient is ambulatory or bed ridden, young or old, obese or gaunt, etc can influence the design of a controlled release product.

3.1) physicochemical properties of a drug influencing drug product design and performance:

1.Aqueous solubility

Since drugs must be in solution before they can be absorbed, compounds with very low aqueous solubility usually suffer oral bioavailability problems because of limited gastrointestinal transit time of the undissolved drug particles and limited solubility at the absorption site.

2.Partition coefficient and molecular size

Partition coefficient and molecular size influence not only the permeation of a drug across biological membranes, but also diffusion across or through a rate-controlled membrane or matrix.

3. Drug stability

The stability of a drug in the environment to which it is exposed is another physicochemical factor to be considered in the design of controlled release systems

4. Protein binding

Blood proteins are for the most part re circulated and not eliminated, drug protein binding can serve as a depot for drug producing a prolonged release profile/ especially if a high degree of drug binding occurs [13].

3.2) biological factors influencing the design and performance of controlled release products

1. Absorption: To maintain constant blood or tissue level of drug, it must be uniformly released from the controlled release system and then uniformly absorbed [14].

2. Distribution

The distribution of drugs into tissues can be an important factor in the overall drug elimination kinetics since it not only lowers the concentration of circulating drug but it also can be rate limiting in its equilibration with blood and extra cellular fluids.

3. Metabolism

Drug metabolism can either turn an inactive drug into an active metabolite or inactivate an active drug. A drug's metabolism might change in a number of tissues, some of

which have more enzymes than others.

4.Duration of action

Naturally, a drug's biological half-life and, consequently, its duration of effect are important factors when deciding whether to use a controlled release medication. The way a substance is eliminated, metabolized, and distributed can all affect its biological half-life.

5. Total clearance (Cl)

The CL is that the hypothetical volume of distribution of un metabolised drug that is cleared per unit of time by any pathway of drug removal.

6. Dosage form Index (DI)

DI is the ratio between the peak (CSS max) and trough (CSS min) values with in dosing intervals [15].

4) PHARMACOKINETICS AND PHARMACODYNAMIC CHARACTERISTICS

4.1 Pharmacokinetic characteristic of a drug

- Absorption rate: When developing Maintaining uniformity in the rate and extent of absorption is crucial for controlled release drug delivery systems. However, the most important stage in determining the rate is the release of the drug from the dosage form
- Biological half-life: Repetitive dosage of a medication with a shorter half-life result in larger variations between maximum steady-state concentrations. As a result, the medication needs to be taken more frequently.
- Metabolism: The metabolism of a medicinal molecule is taken into account while developing Controlled Release (CR) products.

4.2 Drug-Protein Binding: The medication can bind to macromolecules, tissue proteins, plasma proteins, and blood cells.

1] spectrum of treatments: A pharmaceutical utilized in a controlled release drug delivery system must have a broad therapeutic range to ensure that changes in release rates do not lead to concentrations over the desired level.

2] Therapeutic Index (T.I): For formulations requiring sustained release, candidates with a low T.I. are less appropriate. If a drug's T.I. is greater than 10, it is considered safe.

3] Plasma concentration-response relationship: The pharmacological effects of medications such as reserpine are not influenced by concentration, making them unsuitable for use in controlled-release systems [16].

5) TYPES OF CONTROLLED DRUG DELIVERY SYSTEMS

The diversity in controlled drug delivery technologies has resulted in various types of systems that can be applied in different therapeutic areas. These can be broadly categorized into:

1. Oral controlled release system
2. Targeted delivery system
3. Dental systems
4. Ocular systems
5. Transdermal systems
6. Vaginal and uterine systems
7. Injections and implants
8. Mucosal drug delivery system
9. Inhalatin drug delivery system

These can be broadly categorized into

5.1 Oral CDDS

Oral drug delivery remains the most common and preferred route of drug administration due to its convenience and non-invasive nature. The following systems are employed in oral CDDS:

Sustained-Release Tablets:

These tablets are designed to release the drug at a controlled rate over a prolonged period, ensuring constant plasma levels.

Gastro-Retentive Systems:

Some drugs are poorly absorbed in the small intestine but can be better absorbed in the stomach. In such cases, gastro-retentive systems, such as floating tablets and bio adhesive systems are used to ensure the drug remains in the stomach for extended periods, enhancing its absorption [17].

5.2 Transdermal CDDS

Transdermal drug delivery allows drugs to be absorbed directly through the skin into the systemic circulation, bypassing the digestive system and first-pass metabolism. Notable examples include:

Transdermal Patches

These patches have been developed for a variety of drugs, including nicotine, fentanyl, and hormonal therapies [18].

5.3 Targeted drug delivery system

- Transdermal drug delivery allows drugs to be absorbed directly through the skin into the systemic circulation, bypassing the digestive system and first-pass metabolism [19].

5.4) ocular drug delivery system

An ocular drug delivery system is designed to deliver medications to the eye (anterior or posterior segment) in a safe, effective, and targeted way, overcoming barriers like tear turnover, blinking, and limited permeability (20).

5.5) dental system in CDDS, dental cones is typically referred to the cone shaped reference or ocular cones used during digital denture setup to help establish:

1. Jaw relation records
2. Tooth positioning guides [21].

5.6) mucosal drug delivery system

Drug delivery systems that are mucoadhesive are made to stick to mucosal surfaces, including those in the gastrointestinal tract, eyes, nose, mouth, and vagina. Improving drug residence duration at the application site is the primary goal, as this will improve medication absorption and therapeutic efficacy [22].

5.7) veginal / uterine system

These are controlled drug delivery system designed to administer drugs locally or systemically through the veginalroute or directly into the uterus.

5.8). implantable drug delivery system

Implants are designed for the controlled release of drugs over a long period, typically from months to years, without the need for frequent administration. These systems are especially useful for chronic diseases or long-term conditions [23].

6) POLYMERS USED FOR CONTROLLED DRUG DELIVERY SYSTEM

Polymers play a crucial role in drug delivery, serving as binders in tablets, and viscosity. Flow-controlling agents in

liquids, suspensions, and emulsions. Characteristics of Ideal polymer system an ideal polymer system should possess the following characteristics:

1. It should be inert and compatible with the environment.
2. It should be non-toxic.
3. It should be easily administered [24].

Classification: Based upon the mechanism used for obtaining sustained and controlled release of the drug, these systems are classified as follows,

1.Diffusion Controlled System

Diffusion Controlled System Diffusion process shows the movement of drug molecules from a region of a higher concentration to one of lowers concentration [25].

a. Reservoir Type

In the system, a water-insoluble polymeric material encloses a core of the drug, which controls the release rate. Drugs will partition into the membrane and exchange with the fluid surrounding the particle or tablet [26].

b) Matrix Type

A solid drug is homogeneously dispersed in an insoluble matrix and the rate of release of drug is dependent on the rate of drug diffusion and not on the rate of solid dissolution.

Schematic Representation of Monolithic (matrix) Diffusion Controlled Drug Delivery Device.

1. Dissolution Controlled Systems Drugs:

having high aqueous solubility and dissolution rate, show challenges in controlling their dissolution rate [27].

a) Encapsulation Dissolution Controlled Systems:

By using slow-dissolving polymers, microencapsulation procedures coat or encapsulate drug particles. The coating's thickness and solubility determine how quickly it dissolves.

b) Matrix Dissolution Controlled Systems:

Matrix dissolution systems are the most commonly used technique in controlled delivery systems and involve the API being homogeneously distributed throughout a polymer matrix [28].

2.Dissolution and Diffusion Controlled Release Systems:

The drug core is enclosed in a partially soluble membrane. Pores are thus created due to the dissolution of parts of the membrane which permit entry of aqueous medium into the core and hence drug dissolution and diffusion of the dissolved drug out of the system [29].

3. Water Penetration Controlled Systems:

a) Swelling Controlled Systems

Swelling-controlled release systems absorb body fluids and swell, increasing solvent content and polymer mesh size and allowing drug diffusion through swollen network [30].

b) Osmotically Controlled Release Systems:

Every osmotic medication delivery method has an osmotic core and a semi-permeable membrane that regulates water flow.

4.Chemically Controlled Release Systems

Chemically controlled release systems are the systems that change their chemical structure when exposed to biological fluid [31].

5. pH– Independent Formulations

The gastrointestinal tract presents some unusual features for the oral route of drug administration with relatively brief transit time through the gastrointestinal tract, which constraint the length of prolongation, further the chemical environment throughout the length of the gastrointestinal tract is a constraint on dosage form design [32].

6. ALTERED DENSITY FORMULATIONS

Several approaches have been developed to prolong the residence time of the drug delivery system in the gastrointestinal tract like the High-density approach and the Low-density approach [33].

7) ADVANTAGES

1. Enhance patient compliance and convenience.
2. Reduction in dosing frequency.
3. Reduced fluctuations in circulating drug levels.

8) DISADVANTAGES

1. Increased variability among dosage units.
2. Stability problems. Increased variability among
3. Toxicity due to dose dumping.
4. Increased cost.
5. More rapid development of tolerance [34].

9) CURRENT TRENDS

a) Gene and RNA Delivery: With the rise of genetic therapies, CDDS are being adapted for the delivery of nucleic acids:

b) CRISPR-Cas9 Systems: Delivery systems are being developed to transport gene-editing components to target tissues for the correction of genetic disorders.

c) mRNA Vaccines: Lipid nanoparticles have become crucial for delivering mRNA vaccines, as seen with COVID-19 vaccines, marking a significant breakthrough in CDDS for genetic therapies.

d) Bio-Inspired Systems: Utilizing biological entities like viruses or exosomes as carriers for targeted delivery, mimicking natural mechanisms of cellular uptake and transport.

10) APPLICATIONS

Formulations with controlled release have a wide range of uses in several medical fields.

1. Cancer treatment: In cancer treatment, controlled drug delivery systems are used to improve tumour targeting accuracy. By maximizing drug concentration at the target and reducing exposure to healthy tissues, these systems allow anticancer medications to be delivered directly to the tumour location.
2. Cardiovascular diseases: Medications for heart failure, hypertension, and other cardiovascular diseases are administered using controlled drug delivery systems, or CDDS.
3. Transplantation medicine: Controlled drug delivery systems provide a way to provide immunosuppressive medications during organ transplantation, reducing the possibility of organ rejection.
4. Psychiatric Disorders: Controlled release drugs can help stabilize mood and reduce the swings that come with immediate release formulations for diseases like bipolar disorder or schizophrenia [35].

11) LIMITATIONS

- Complex Manufacturing: The development and production of CDDS can be technically complex and expensive, requiring specialized equipment and expertise.
- Regulatory Challenges: Obtaining regulatory approval for novel CDDS can be difficult due to stringent safety and efficacy requirements [36].
- Risk of Dose Dumping: If a controlled release mechanism fails, there is a risk of sudden drug release (dose dumping), leading to potential toxicity.

12) FUTURE DIRECTIONS

Future directions in Controlled Drug Delivery Systems (CDDS) focus on enhancing precision, efficacy, and patient adherence through personalized, smart technologies. Key innovations include nanotechnology-based targeting, stimuli-responsive (smart) materials, 3D-printed, patient-specific devices, and AI-driven, bio-membrane-camouflaged systems to revolutionize therapeutic delivery.

13) CONCLUSION

To enhance flavor and stability, drugs and excipients are mixed together in dosage forms. Conventional dose forms require frequent administration and patient cooperation due to their incapacity to regulate plasma drug levels. Controlled drug delivery systems improve bioavailability, release, and sustain plasma levels with minimal side effects. These systems include water penetration, dissolution, diffusion, and chemically controlled distribution. In the treatment of diseases, delivery systems that react to stimuli are useful. Future drug delivery will focus on patient-specific therapy using CRISPR-cas9-based systems, 3D-printed devices, and microfluidic-based devices.

14. AUTHOR CONTRIBUTIONS

All authors are contributed equally.

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16. DECLARATION COMPETING INTEREST

The authors have no conflicts of interest to declare.

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