Journal of Current Pharma Research (JCPR)

Volume 20, Issue 9, September 2024 **jcpr.humanjournals.com** ISSN: 2230-7842, 2230-7834

Innovations and Techniques in Oral Controlled Release Systems: A Comprehensive Review of Tablet Characterization Methods

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Received: 2024-09-02 Revised: 2024-09-19 Accepted: 2024-09-23

ABSTRACT

The oral route of drug administration is widely recognized as the most convenient and safest method, particularly suitable for a broad range of patients including both children and the elderly. Among various drug delivery systems, controlled release formulations have emerged as a significant innovation in pharmaceutical development. The oral route is particularly advantageous for these systems due to its ease of use and adaptability across different age groups. Controlled release systems are designed to deliver drugs in a regulated manner to specific sites within the body via oral administration. These systems include several types, such as diffusion-controlled, dissolution-controlled, osmotically controlled, ion-exchange controlled, hydrodynamically balanced, multi-particulate, and microencapsulated drug delivery systems. Each type utilizes a range of natural, semi-synthetic, and synthetic polymers in their formulation. This review aims to explore the various oral controlled release drug delivery systems, the polymers involved in their formulation, and the characterization techniques used to evaluate tablet dosage forms.

Keywords: Oral route, Controlled release drug delivery system, Tablets characterizations

INTRODUCTION

Oral drug delivery remains one of the most effective and reliable methods for administering medications due to its ease of use and convenience. Traditional dosage forms often provide limited control over therapeutic response throughout the dosing interval. However, recent advancements in oral drug delivery technology have significantly enhanced the pharmaceutical industry's ability to improve dosage forms. Innovations in drug delivery systems are now harnessing unique features to achieve optimal outcomes with fewer drawbacks. Novel drug delivery systems (NDDS) play a crucial role in this evolution, offering enhanced therapeutic efficacy, reduced toxicity, and improved stability profiles[1].

Oral drug delivery system can be categorized into

(1) Targeted release formulations

(2) Sustained release formulations and

(3) Immediate release formulations.

Immediate release formulations are often preferred for achieving a rapid onset of action with certain drugs, such as analgesics, antipyretics, and vasodilators. However, sustained release (SR) drug delivery systems have become increasingly important in pharmaceutical science due to their numerous advantages over traditional solid oral dosage forms.

Key benefits of SR systems include:

1. Maintaining serum drug concentrations within the therapeutic range for extended periods.

2. Predictable and controllable drug release rates over specific time intervals.

3. The ability to extend the action of drugs with shorter half-lives.

4. Reduced frequency of dosing, which improves patient adherence and minimizes drug wastage[2].

To achieve targeted delivery, systems have been developed that direct drugs to specific areas within the body. Conventional tablets can be enhanced with pH-sensitive coatings and site-specific ligands for more precise targeting.

Currently, there is a growing interest in delivering active pharmaceutical ingredients (APIs) to specific sites, particularly to minimize side effects and improve therapeutic efficacy. This targeted approach is especially valuable in fields such as chemotherapy and the treatment of genetic disorders.

Advanced delivery systems, including liposomal formulations, nanoparticles, resealed red blood cells, and prodrugs, are employed to address these goals by directing drugs to molecular pathways and targeting the underlying causes of diseases[3,4].

1 CLASSIFICATION OF ORAL CONTROL RELEASE DRUG DELIVERY SYSTEMS[5,6]

It can be classified on the basis of drug released pattern. Generally, the oral sustained release formulations are categorized as given below:

1. Diffusion controlled drug delivery systems

2. Dissolution controlled drug delivery systems

3. Osmotically controlled drug delivery systems

4. Ion-exchange controlled drug delivery systems

5. Hydrodynamically balanced systems

- Multi-Particulate drug delivery systems

- Microencapsulated drug delivery system

2 Diffusion controlled drug delivery system[7]

A system is classified as diffusion-controlled when the release of the drug is regulated by the process of diffusion. In such systems, drug release occurs through a non-reactive, immobile membrane made from insoluble polymeric materials. Additionally, diffusion-controlled systems can be further categorized into:

i. Matrix system

ii. Reservoir system

i. Matrix system

In this dosage form, the drug is uniformly distributed within a polymeric matrix, as illustrated in Figure 1. In these systems, the active agent located in the outer surface layer, which comes into contact with the dissolution medium, first dissolves and is subsequently released through diffusion across the matrix. Mathematical models used to describe these systems are based on the following key assumptions:

(a) A quasi-steady state is typically maintained during the drug release process. (b) The thickness of the particulate dosage form is minimal compared to the average distance the drug molecules travel during diffusion through the matrix, which is greater than the diameter of the dosage form. (c) The area where the solution is received maintains an ideal sink condition. (d) In the matrix system, the diffusion coefficient remains constant, and there are no changes in the function or integrity of the polymeric membrane. The matrix system is shown in figure 1.

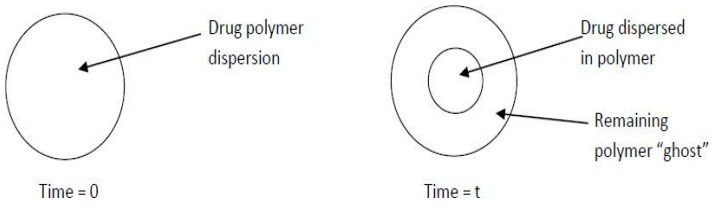


Figure 1: Matrix diffusion system

Release of the drug can be controlled by changing the parameters given below:

- Initial concentration of drug in the matrix
- Aperture size of the inert membrane
- Combination of the polymers used in the matrix
- Drug solubility

This system presents several advantages, including ease of formulation, the capability to incorporate high molecular weight compounds, and the prevention of dose dumping due to unintended leakage. However, there are some limitations associated with this system. Achieving a perfectly zero-order release is challenging. In the case of implantable systems, the insoluble matrix remains in place even after the drug has been released and needs to be removed.

The matrix system is straightforward to formulate and is particularly effective for delivering high molecular weight drugs to specific target sites. The drug is uniformly distributed within the matrix, which helps to prevent rapid release of the drug contents.

Main disadvantages are:

- The elimination of exhausted polymeric material from body is difficult.
- Zero order release in typically difficult to attain

ii. **Reservoir system**

In a reservoir system, the drug is contained within a core that is encased by a polymeric membrane, which regulates the release rate of the drug from the device (Stevenson et al., 2012). Key characteristics of reservoir systems include:

- Different polymeric membranes can be used to achieve various release rates of the drug.
- Using reservoir type system Zero order release can be attained.
- By altering membrane character drug release pattern can be controlled.

These systems have few drawbacks such as;

- The implanted systems should be detached physically.
- It's too difficult to add in drugs with high molecular weight in this system because membrane aperture size restricts the size of the active substances.
- Can be the cause of increased toxicity in case of system collapse
- High production cost

3 A diffusion-controlled matrix device is designed to provide a continuous release of a drug at a steady state. However, there may be initial variability in the drug release pattern, which can result in either higher or lower release amounts depending on the characteristics of the device. When a device is used soon after its production, it may exhibit a slower release rate due to a lag period required for the drug to diffuse through and penetrate the controlling membrane. This membrane regulates the release rate. Conversely, if the device is stored for an extended period, the drug may gradually saturate the membrane, potentially leading to a more immediate release upon use.

4 Dissolution controlled drug delivery systems[8,9]

Drugs with a slow dissolution rate naturally exhibit sustained-release characteristics, as the limited dissolution rate controls the drug's release from the formulation. This property can be harnessed to develop sustained-release formulations by reducing the dissolution rate of hydrophilic drugs. This can be achieved through several methods:

- **Formulating appropriate salt derivatives**: Using specific salt forms of the drug can alter its dissolution behavior.
- **Applying slow-dissolving coatings**: Coating the drug with materials that dissolve slowly can help control its release.
- **Utilizing dissolution-controlled matrix systems**: Incorporating the drug into a matrix system with carriers that dissolve slowly can effectively manage the release rate.

4o mini

5 Osmotically Controlled Drug Delivery System[10,11]

In an osmotically controlled drug delivery system, an osmotic agent is incorporated into the formulation. The drug, which must be water-soluble, is combined with an osmotic agent like sodium chloride and encased in a selectively permeable membrane, often made from cellulose derivatives such as cellulose acetate. This system might also use an impermeable outer membrane. Small openings, created through mechanical or laser drilling, are made in the tablet to allow drug release. Water diffuses through the semi-permeable membrane, dissolving the drug, which then exits through the orifice. The osmotic pressure gradient between the inner core and the external environment drives the drug release.

Osmotic systems offer advantages over other delivery methods by providing zero-order release kinetics. They also allow for the combination of incompatible drugs in a single dosage form and are unaffected by gastrointestinal pH or food intake. However, their quality control is complex, making them relatively expensive.

6 Ion-Exchange Controlled Drug Delivery System[12,13]

Ion-exchange controlled drug delivery systems use cross-linked water-insoluble polymers containing repeating salt-forming functional groups. When the dosage form encounters ion-exchange resins in the dissolution medium or gastrointestinal tract, ions such as Na+, H+, Cl-, or OH- are exchanged, leading to the release of the drug bound to the resin. The drug-resin complex can be prepared by either prolonged contact in a solution or repeated exposure in a chromatographic setup. The rate of drug release depends on factors like the site of release, the distance the drug must travel, and the properties of the resin system. This system is particularly useful for drugs prone to enzymatic degradation.

7 Hydro-Dynamically Balanced Drug Delivery System[14]

Hydro-dynamically balanced drug delivery systems address the challenge of short gastric residence times by using floating systems. These systems are designed with a lower bulk density compared to gastric fluids, allowing them to float in the stomach for extended periods, thereby enhancing the bioavailability of the therapeutic agents. Such systems can also provide sustained, localized drug release in the stomach, achieving targeted therapeutic effects. The drug is typically layered over a buoyant core that makes the system lighter than the gastric contents.

8 Multi-Particulate Drug Delivery Systems[15]

Multi-particulate drug delivery systems involve dispersing the therapeutic substance onto beads, pellets, granules, or similar particulate forms. The drug is distributed onto substrates such as sugar spheres or microcrystalline cellulose beads, which are then coated using methods like pan coating or air suspension. The particles vary in size, with nonpareil seeds ranging from 425 to 850 µm and microcrystalline spheres from 170 to 600 µm. These spheres are durable and can be compressed into small tablets (3 to 4

mm in diameter) that are filled into gelatin capsules, containing 8 to 10 mini tablets. Some tablets provide immediate release, while others are coated for sustained release.

9 Microencapsulated Drug Delivery System[16]

Microencapsulation involves enclosing solids, liquids, or gases within a thin coating. Gelatin is commonly used for this purpose, but synthetic polymers such as polyvinyl alcohol, ethyl cellulose, and polyvinyl chloride are also utilized. This technique can encapsulate a variety of substances, including proteins, lipids, and drugs, to control the release and protect the encapsulated material.

10 RELEASE CONTROL POLYMERS USED IN SUSTAINED RELEASE ORAL CONTROL DRUG DELIVERY SYSTEM[17,18]

A wide variety of Polymers can be used in formulating the sustained release oral control drug delivery system. Classification of the polymers is usually based on the features of the matrix system.

Polymers can be classified in the following classes.

11 Natural polymers

12 Natural polymers like xanthan gum, pectin, guar gum, gum acacia, and tragacanth are widely utilized in pharmaceutical formulations for various dosage forms, including oral and topical preparations. These polymers offer several benefits when used in matrix systems to create sustained-release dosage forms. Typically, they possess hydrophilic properties, which contribute to their effectiveness in controlling drug release. Under physiological conditions, these natural polymers are generally non-toxic and can also serve as valuable food ingredients.Xanthan gum.

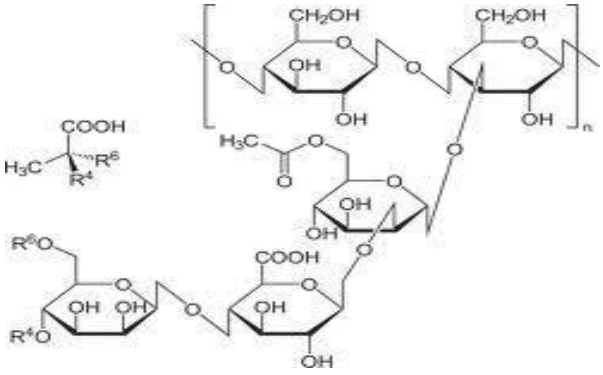


Figure 2: Structural formula of Xanthan

Xanthan Gum

Xanthan gum is a fine, cream- or white-colored powder known for its excellent flow properties and lack of color or odor. It is a polysaccharide with a molecular weight ranging between 4 to 12 million g/mol. Xanthan gum is also referred to by several names including Xantural, E415, Keltrol, Polysaccharide B-1459, Rhodigel, Corn Sugar Gum, and VanZan NF. It has a pH of 6.0 to 8.0 when dissolved in a 1% w/v aqueous solution. While xanthan gum is insoluble in ether and ethanol, it readily dissolves in water. The structural formula of xanthan gum is depicted in Figure 2.

Pectin

Pectin appears as a coarse or fine powder, ranging from yellow to white, and has an odorless, mucilaginous taste. Its chemical name is pectin, and it has a molecular weight between 30,000 and 100,000. It is also known by various names such as citrus pectin, E440, methopectin, methyl pectin, methylpectinate, mexpectin, and pectinic acid. Pectin typically has a pH range of 6.0 to 7.2. It is soluble in water but insoluble in 95% ethanol and other organic solvents. The structural formula of pectin is shown in Figure 3.

Journal of Current Pharma Research (JCPR)
Volume 20, Issue 9, September 2024 jcpr.humanjournals.com ISSN: 2230-7842, 2230-7834

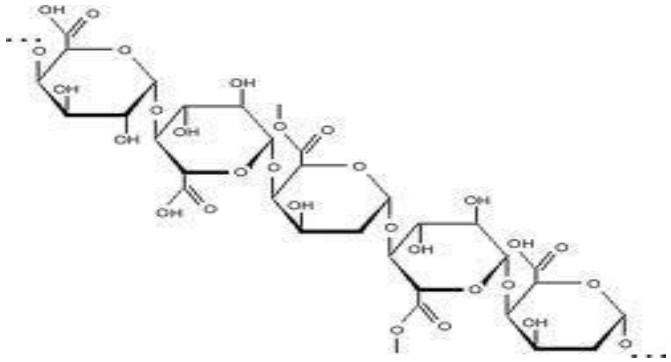


Figure 3: Structural formula of Pectin

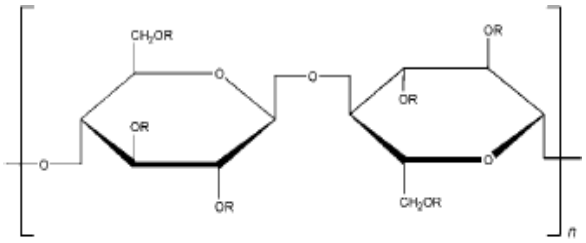
Semi-Synthetic Polymers

Semi-synthetic polymers are widely utilized in the formulation of oral controlled drug delivery systems. These polymers typically swell upon contact with water, forming a gel layer that serves as a barrier to drug release. Examples include Hydroxypropyl Methylcellulose (HPMC), Hydroxyethyl Cellulose (HEC), Galactomannan, Sodium Carboxymethyl Cellulose, Carboxypolymethylene, Methylcellulose, and Sodium Alginate. The gel layer formed by these polymers helps regulate drug release through the matrix. The rate of drug release is influenced by the ratio of drug to polymer and the characteristics of the polymeric material, with both diffusion and erosion playing roles in the release mechanism.

For instance, low molecular weight polymers like Methylcellulose may lead to drug release through erosion due to the limited duration of the hydrated gel film. On the other hand, Carboxymethylcellulose, an anionic polymer, can interact with cationic drugs, potentially increasing dissolution in the intestinal tract.

Hydroxypropyl Methylcellulose (HPMC)19,20

Hydroxypropyl Methylcellulose (HPMC) is a granular powder that ranges from white to creamy white and is devoid of odor and taste. Its chemical designation is Cellulose Hydroxypropyl Methyl Ether, with a molecular weight varying from 10,000 to 1,500,000. It is known by several names, including HPMC, Methocel, Methylcellulose Propylene Glycol Ether, Methyl Hydroxypropyl Cellulose, Metlose, and Tylopur. In a 1% w/w aqueous solution, HPMC has a pH range of 5.5 to 8.0. The bulk density of HPMC is 0.341 g/cm³, the tap density is 0.557 g/cm³, and the true density is 1.326 g/cm³. Its glass transition temperature falls between 170°C and 180°C. The structural formula of HPMC is illustrated in Figure 4.



where R is H, CH_3, or $CH_3CH(OH)CH_2$

Figure 4: Structural formula of HPMC

Insoluble Inert Matrix Forming Polymers21

Insoluble, non-biodegradable polymers are commonly used to create matrix systems for controlled drug delivery. These polymers, such as Ethyl Cellulose, Polyethylene, Polyvinyl Chloride, and Methylacrylate-Methacrylate Copolymer, swell but do not break apart within the gastrointestinal tract. They are typically selected for their suitable compression properties, and can be processed through direct compression or, less commonly, wet granulation before compression. Drug release in these systems is primarily governed by the rate at which liquid penetrates the matrix. Adding wetting agents and pore formers can enhance liquid penetration, thereby influencing the drug release rate through diffusion and/or dissolution.

Insoluble Erodible Matrix Forming Polymers22

Matrix systems made from hydrophobic substances like lipids, waxes, and related materials control drug release through both diffusion and erosion. Examples include Castor Wax (polyethylene glycol monostearate), Carnauba Wax (which may include stearyl alcohol, stearic acid, and polyethylene glycol), and various triglycerides. The presence of a lipid core can partially encase the drug, making complete release challenging. The introduction of surfactants can improve water penetration into the matrix, thus enhancing drug release through matrix erosion.

Biodegradable Polymers23

Biodegradable polymers are derived from cyclic lactones that polymerize to form polyesters, such as Polylactic Acid (PLA) and Poly(lactic-co-glycolic acid) (PLGA). These copolymers, composed of glycolic acid and lactic acid, exhibit reduced crystallinity and increased degradation rates when mixed. Typically used in ratios of 50:50 for matrix systems, the specific concentration can be adjusted to achieve desired degradation rates. These polymers are also utilized as suturing materials for internal injuries due to their ability to degrade naturally in the body. Additionally, water-insoluble polymers like Polycaprolactone can extend the lifespan of these materials by hindering water influx and reducing degradation rates.

Characterization of Oral Controlled Release Tablets24,25,26

Weight Variation

This parameter assesses the consistency of drug content across tablets by measuring the weight of 20 randomly selected tablets and calculating the average weight. Variations in tablet weight can indicate differences in drug content.

Hardness Test

Hardness, or crushing strength, measures the force required to break a tablet. This test evaluates tablet durability and can affect friability, disintegration time, dissolution, and bioavailability. The hardness of 20 randomly chosen tablets is measured using a hardness tester, and the average value is calculated.

Thickness Test

The thickness of a tablet reflects the amount of material and pressure applied during compression. Variations in thickness can occur due to differences in material density and compression pressure. Thickness is measured with a vernier caliper for 20 randomly selected tablets, and the average thickness is determined.

Friability Test

The friability test assesses a tablet's ability to withstand mechanical stress and abrasion during manufacturing, packaging, and handling. In this test, 20 tablets are subjected to 25 rpm for 4 minutes in a friabilator. The percentage of weight loss, calculated before and after the test, should not exceed 1.0% according to compendial standards.

Content Uniformity Test

To ensure uniform drug content, ten tablets from each batch are tested. A powdered sample equivalent to the active drug is extracted with a suitable solvent, heated at 40°C for 15 minutes, and then filtered. The absorbance of the solution is measured using a spectrophotometer, and the drug content is determined by comparing it to a reference solution of the same concentration.

Drug Release Studies

Dissolution testing of oral controlled-release formulations is conducted using USP Apparatus II (paddle method) with 900 ml of dissolution media at 37°C (±5°C) and 50 rpm. Samples are taken at specified intervals and analyzed using spectrophotometric methods. The release profile is evaluated with software to determine the time required for 50% drug release using cubic spline interpolation.

Release Kinetics Models 27,28

Various kinetic models are employed to understand the drug release patterns from oral controlled-release systems. These models help predict drug behavior and the release kinetics, providing insights into how the drug is released over time.

These are given as:

Zero order models

$$Q1=Q0+kot \qquad \text{(i)}$$

Where k0 is the release rate constant Qt is the amount of drug released at any time interval.

1st order model

$$\log Qt = \log Q0 + K1t/2.303 \qquad \text{(ii)}$$

k1, is the 1st order release rate constant Qt, is the amount of drug released at any time interval.

Higuchi model

$$Ft = KHt1/2 \qquad \text{(iii)}$$

KH, is release rate constant for Higuchi model.

Korsmeyer Peppas model29

$$Mt/M0 = kKPtn \qquad \text{(iv)}$$

K kp, is release rate constant for Korsmeyer peppas model $Mt/M0$, is the amount of drug release at time t and infinity n, is the diffusional constant

Hixon-Crowell model30

$$W\ 1/3 - W\ 1/3 = Kt \qquad \text{(v)}$$

$$0\ t \qquad S$$

Ks, is release rate constant for Hixon-Crowell model.

CONCLUSION

Oral controlled drug delivery systems represent a safe, effective, and convenient method for drug administration. These systems utilize various techniques to deliver medications in a controlled manner, thereby enhancing their bioavailability as they traverse the gastrointestinal tract. By providing a consistent and predictable release of the drug, these systems can significantly improve patient compliance and treatment outcomes.

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How to cite this article:
Dr. K. Venkata Gopaiah et al. Jcpr.Human, 2024; Vol. 20 (9): 16-24

Conflict of Interest Statement:
The authors have no conflicts of interest to declare.