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Review TDD

Review on Sustained-Release Matrix Tablet

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Abstract

Pharmaceuticals often use sustained release dose forms to prolong the therapeutic agent's presence in the bloodstream and maintain a consistent plasma profile. The matrix governs the drug's release rate. Hydroxypropyl methyl cellulose, a release retardant, is a key excipient in formulations due to its ability to promote sustained release. Techniques that include wet granulation, direct compression, or the dispersion of solid particles within a porous matrix, integrating polymers, like polymethyl methacrylate, polyglycolic acid, and hydroxypropyl methyl cellulose, are utilized to generate sustained release matrix tablets. The procedure involves compressing a blend of medicine, retardant material, and additives to create a tablet with the drug contained in the retardant matrix core. The drug reservoir in a matrix diffusion-controlled system is generated by evenly dispersing particles throughout a hydrophilic or lipophilic polymer matrix. Matrix devices offer benefits, such as enhanced patient compliance, fewer fluctuations in steady-state medication levels, optimal drug utilization, and increased safety margins for powerful drugs. The matrix tablet continuously releases the medication by controlled diffusion and dissolution. Hydrophilic polymers with strong gelling capability are much sought after for matrix tablet applications.

Keywords: Sustained release, matrix tablet, drug delivery systems, hypothetical plasma drug concentration, hydrophilic matrix tablet.

INTRODUCTION

It is known that the term "sustained release" has been used for many years in pharmaceutical and medical literature. It is widely used to characterize a pharmacological dosage form designed to postpone the release of a therapeutic drug, resulting in a prolonged and/or delayed appearance in the systemic circulation, as well as a sustained plasma profile over time. Its pharmacological action frequently takes time to start, and its therapeutic effect lasts for a long time [1]. The primary method used to administer medications is orally. The most common oral dose form is tablets, which are utilized by both physicians and patients.

Conventional formulations require repeated doses for long-term therapy to be effective in treating chronic illness conditions, which has several drawbacks [2].

Because matrix tablets utilize conventional technology, have fewer processing variables, and can hold high drug dosages, they are thought to be the most economical sustained-release dosage forms (SRDFs). The drug release is slowed down by the matrix system, which is composed of the drug plus a variety of components [3]. There are multiple subclasses of this system, namely mineral matrices, hydrophilic matrices, lipid matrices, hydrophobic matrices, and biodegradable matrices [4].

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The simplest meaning of sustained release is any medication, dosage form, or drug that prolongs the therapeutic impact of the drug (Figure 1) [5].

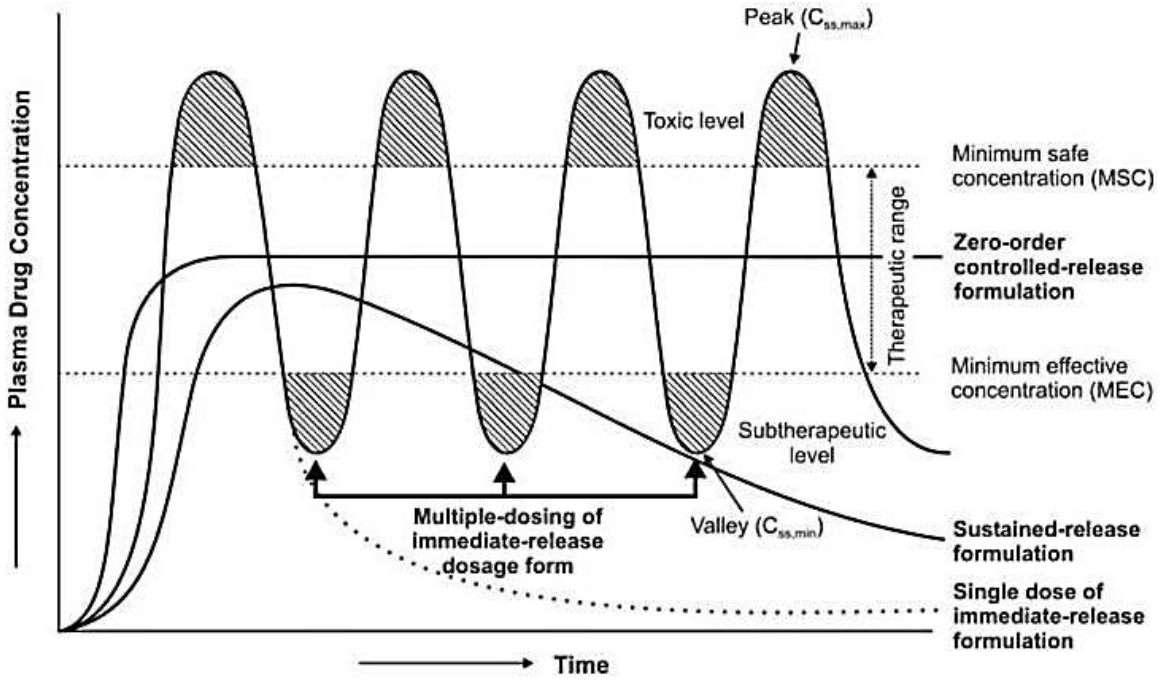

Figure 1. Hypothetical plasma drug concentration profile for immediate release, sustained release, and controlled release dosage forms [5].

OBJECTIVE

Most drug delivery systems will still be oral sustained-release medications. This work aims to improve bioavailability by formulating pills that prevent first-pass metabolism. This study aimed to create a sustainable release method that could maintain consistent plasma concentrations for up to 24 hours. Reason for selecting API as a model medication [6]. Less variability between and within subjects and reduced chance of dosage dumping [7].

Drawbacks

1. Poor patient compliance can lead to missed medicine doses.
2. Unavoidable changes in drug concentrations may result in under- or overmedication [7].

Advantages [8–9]

1. Easy to manufacture.
2. Versatile and affordable.
3. Capable of releasing high-molecular-weight molecules.
4. Sustained release formulations can maintain therapeutic concentrations for extended periods.
5. Sustained-release formulas avoid excessive blood concentrations.
6. Sustained-release formulations can increase patient compliance.
7. Reduce toxicity by slowing drug absorption.

Disadvantages [10]

1. Ineffective formulations can cause dose dumping.
2. Less room for dosage adjustments.

3. The cost exceeds that of normal dose forms.
4. Enhance the potential for first-pass metabolism.

PRINCIPLE OF SUSTAINED-RELEASE DRUG DELIVERY SYSTEMS [11–12]

Conventional dose forms facilitate the release and absorption of active substances. The solution of medication at the absorption site is referred to as an absorption pool. The initial constants of rate for drug absorption, release, and elimination are represented by Ke, Kr, and Ka, respectively. As drug release starts promptly at ordinary doses, Kr becomes significantly larger than Ka. Kr is less than Ka for dosage forms with non-immediate release, showing that the drug's release is the rate-limiting step. The equation indicates zero-order kinetics: Kr = Rate In = Rate Out = Ke Cd Vd.

- where *K:* Zero-order rate constant for drug release-amount/time.
- *K:* First-order rate constant for overall e drug elimination time.
- *C:* Desired drug level in the d body – Amount/volume.
- *V:* Volume space in d 4 which the drug is distributed in liters.

CHARACTERISTICS OF DRUGS THAT ARE UNSUITABLE FOR ORAL SUSTAINED RELEASE FORMS [13]

Characteristics Drug

1. Not well absorbed in the lower intestine: riboflavin, ferrous salts.
2. Rapid absorption and excretion, with a biological Penicillin G, Furosemide half-life of less than 1 hour.
3. A medication with low therapeutic indices that provides phenobarbital, digitoxin cumulative action, and beneficial side effects.

Factors Considered in Dosage Form Design

There are primarily two types of elements that influence dosage form design.

BIOLOGICAL FACTORS [14]

- *First-Pass Effect:* Pharmaceuticals that have a significant first-pass effect deliver their therapeutic effects more than their elimination slowly, which affects their bioavailability.
- *Half-Life:* A drug's half-life is the amount of time it survives in the body. A medicine's dose form may require greater drug concentration if its half-life is short (less than two hours).
- *Side effects:* Prolonging medication release may result in unwanted side reactions.
- *Solubility and Absorption:* The two are inextricably related. Incorporating poorly water-soluble medicines can reduce total absorption efficiency.
- *Duration of Activity:* Biological half-life, or duration of action, is crucial. Drugs with a half-life of 2–7 hours are suitable for SRDF. Drugs with a biological half-life of less than two hours, such as furosemide, should be avoided. A medication having a half-life of more than 8 hours exhibits continuous action. Physiochemical factors [15].
- *Drug Stability:* Sustained release systems aim to distribute contents throughout the gastrointestinal tract, making unstable medications unsuitable for this method. Colonic bacteria play a crucial role in maintaining intestinal pH, enzymes, and microbial flora stability.
- *Aqueous Solubility and pKa:* The pharmaceutical product break down and enters the absorbing membrane after disintegrating in the aqueous phase close to the delivery point. A drug's physicochemical qualities, such as water solubility and pKa for soft acids, significantly impact its absorption. These qualities prioritize a key part in the effectiveness of controlled release strategies. Drugs with high aqueous solubility have low degradation rates and are prone to oral bioavailability issues.
- *Drug Protein Binding:* The degree of protein binding determines drug retention in the vascular space. Drugs with strong protein binding lengthen half-life. These medications do not require an SRDF.

CRITERIA TO BE MET TO INCORPORATE THE DRUG INTO SRDF

To manufacture a medicine for prolonged release, certain physicochemical aspects must be considered, including knowledge of the drug's absorption route from the gastrointestinal system (Tables 1–2).

Table 1. Physicochemical parameters for drug selection.

Parameter	Criteria
Molecular size	<1000 Daltons.
Aqueous solubility	More than 0.1 mg/ml for pH 1–7.8.
Apparent partition coefficient	High.
Absorption mechanism	Diffusion.
General absorbability from all GI segments	Release should not be altered by pH or enzyme.

Table 2. Pharmacokinetic parameters for drug selection.

Parameter	Comment
Elimination half-life	Between 2 and 8 hours.
Absolute bioavailability	Should be 75% or more.
Absorption rate constant (Ka)	Must be higher than release rate.
Elimination rate constant	Required for design.
Total clearance	Not depends on dose.
Therapeutic concentration (Css)	The lower Css and smaller Vd, the less of drug required.

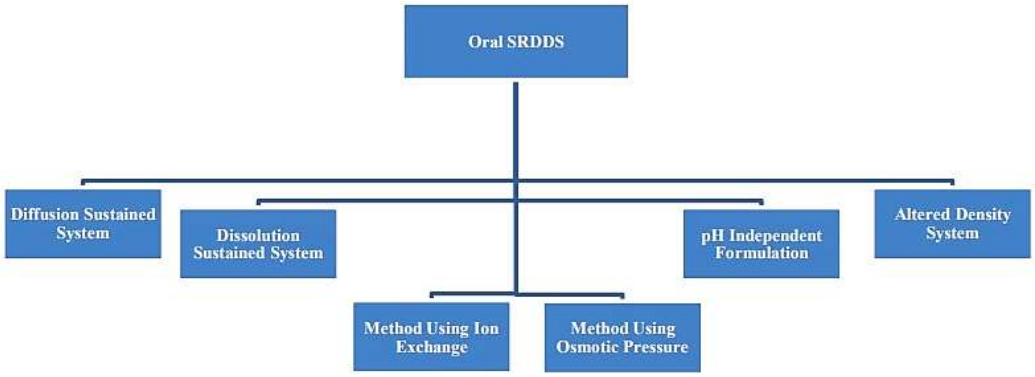

Figure 2. Classification of Oral sustained release drug delivery systems (SRDDSs) [16].

- *Diffusion Sustained System:* Drug molecules move from higher concentration to lower concentrations. The drug flux is calculated as:

  $J = -D\, dc/dx.$

  D = diffusion coefficient in area/time. dc/dx = change of concentration "c" with distance "x".
- *Diffusion Reservoir System:* In this method, a water-insoluble polymeric substance covers a core of medication (Figures 2–4).

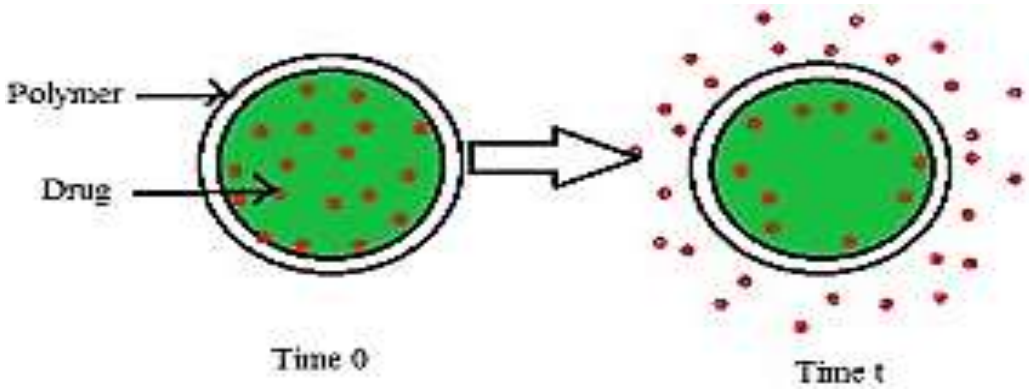

Figure 3. Diagrammatic representation of diffusion-type reservoir system.

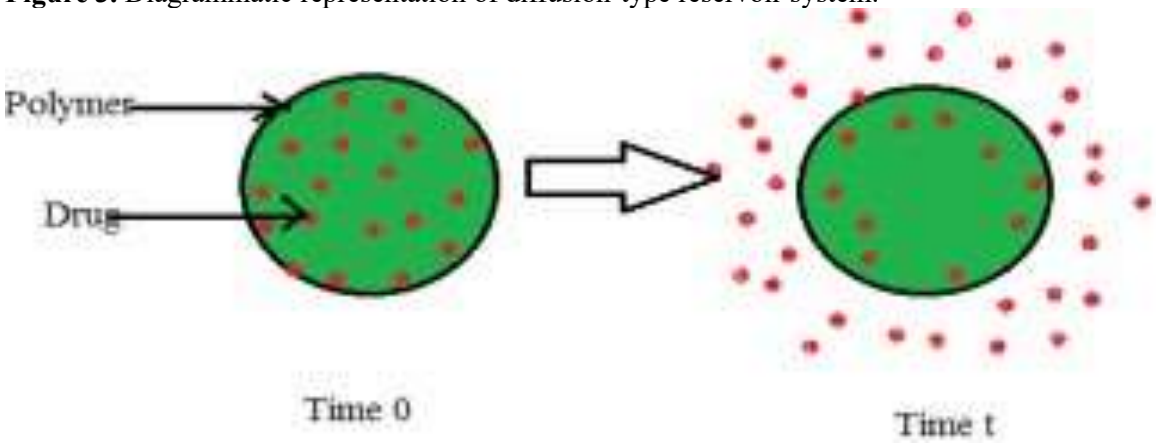

Figure 4. Diagrammatic representation of diffusion-sustained drug release system.

- *Diffusion Matrix Type:* The release rate of solid medication is determined by its distribution in an insoluble matrix and the rate of diffusion and disintegration.
- *Dissolution Sustained Systems:* By delivering relevant salts or derivatives, this compound delays the dissolution of extremely water-soluble pharmaceuticals. Enteric-coated dosage forms frequently use these methods. To protect the stomach from medications, like aspirin, a protective coating is added that dissolves in neutral or alkaline water. When the gut pH is suitable, the medication is released.
- *Ion Exchange Resin:* Zero-order release is the result of this continuous drug delivery technique, which depends on the resin's ionic environment and is not as affected by external variables, such as pH and enzyme involvement at the absorption site. This method provides kinetic outcomes that are satisfactory.
- *pH-Independent Formulations:* Using pH-independent drug release alternatives, including amino acid salts, citric acid, phthalic acid, phosphoric acid, and tartaric acid, can assist in maintaining a consistent pH. To create a buffered sustained release formulation, combine a simple or acidic product with buffering agents, granulate with pharmaceutical excipients, then cover with a permeable polymer containing gastrointestinal fluid.
- *Altered Density:* Only limited use results from insufficient medication release in the gastrointestinal tract. To address this, techniques have been devised to extend the drug's stay in the GI tract.
- *Matrix Tablet:* The word "matrix" describes a three-dimensional network containing the medication as well as the solvents and excipients essential for its organization. Using both diffusion-controlled and dissolution-controlled methods, matrix drug delivery devices are made for continuous drug release. These methods are frequently used for prolonged release because they enable medication to be dissolved or transported in a constant and regulated way [17].

CLASSIFICATION OF MATRIX TABLET [18]

On the Basis of Retardant Material

a) Hydrophobic matrices (plastic matrices).
b) Lipid matrices.
c) Hydrophilic matrices.
d) Biodegradable matrices.
e) Mineral matrices.

Based on Porosity of Matrix

a) Macroporous systems.
b) Microporous systems.
c) Nonporous systems.

Based on Retardant Material

Hydrophobic Matrices

In 1959, the concept of utilizing hydrophobic or inert substances in tablets with matrix was first proposed. The medication is infused with an inert or hydrophobic polymer and smashed into a tablet that delivers extended release in an oral dose form. As the dissolved medication diffuses via the channels created between the compressed polymer particles, constant dissolution takes place. Whereas insoluble polymers have been used, polymers are not always necessary to regulate drug release in this method. Water-insoluble compounds, such as glycerides, fatty acids, waxes, and polymeric components, like methyl and ethyl cellulose, are important factors affecting the release rates of hydrophobic matrix.

Lipid Matrices

These matrices are generated using lipid waxes and other components. Drugs are released from these materials by pore diffusion and erosion. The emission properties are more impacted by the digestive fluid's composition than by an entirely insoluble polymer matrix.

Hydrophilic Matrix Tablet

Using hydrophilic matrix systems is one of the most potential drug delivery strategies. Due to their versatility, cost effectiveness, and regulatory approval, these systems are frequently used to regulate drug release rates. Drug components are uniformly dispersed inside a framework of hydrophilic polymers, such as cellulose derivatives, sodium alginate, xanthan gum, polyethylene oxide, or Carbopol, which expand when exposed to water. These forms of medicine are known as hydrophilic matrix tablets. These technologies are known as swellable-controlled release systems. The observed release rate may indicate a zero-order release. Compression is the most common method for creating commercial hydrophilic matrices. The basic methods for preparing the matrices are like those for traditional tablets.

Biodegradable Matrices

Biodegradable matrices are generated by the interaction of polymers with unstable functional groups at their core. When these matrices are broken down by enzymes made by living cells, biological degradation takes place. Alternatively, monomers and oligomers break down during non-enzymatic degradation. Proteins and carbohydrates are examples of natural polymers; synthetic organic polymers are also used. Other examples include synthetic polymers like polyanhydrides and aliphatic polyesters.

Mineral Matrices

Polymers derived from various types of seaweed can be found within mineral matrices. Alginic acid is one such example – a hydrophilic carbohydrate obtained from brown seaweed species through extraction with diluted alkali.

Based on Porosity of Matrix

Drug molecules spread throughout the matrix, resulting in prolonged release (Figure 5).

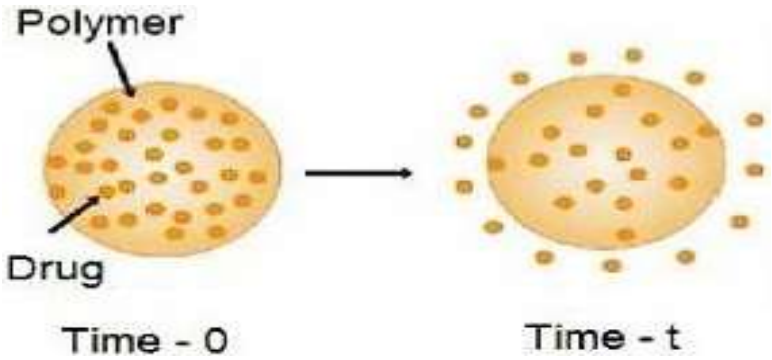

Figure 5. Diffusion of drug across the matrix.

- *Macro Porous Systems:* The holes in this matrix range from 0.1 to 1 μm, bigger than the diffusant molecule size. In this type of mechanism, drugs permeate through these holes.
- *Micro Porous Systems:* Permeation of drug molecules occurs through pores of sizes ranging from 50 to 200Å.
- *Nonporous Systems:* These systems contain no holes. Molecules diffuse via network meshes. There is no pore phase, but the polymeric phase is present.

MECHANISM OF DRUG RELEASE FROM MATRIX SYSTEM [19–21]

- *Diffusion Method:* The medication first breaks down in the outermost layer that comes into contact with the surrounding solution before diffusion out of the matrix. As the solid pharmaceutical interacts with the bathing fluid, the interface in the body moves in an alternate way. The rate at which drug particles disintegrate within the matrix must be greater than the rate at which the dissolved drug exits the matrix to ensure effective dispersion control in this system.
- *Bimodal Release:* In some systems, the active component releases in a bimodal fashion. Diffusion is a part of this process. Extended-release drugs may get hydrated and disintegrate, resulting in release during erosion. Polymer dissolution changes the diffusion path length, making it challenging to represent these complicated systems numerically.

Steps in Bimodal Release of Matrix Tablet

- A water concentration gradient at the polymer/water interface causes water to absorb into the matrix.
- Water absorption causes the polymer to swell.
- When in contact with water, the medication dissolves and diffuses from the matrix.
- Increasing water content significantly boosts the drug's diffusion coefficient.
- *Higuchi Mode:* The Higuchi model releases drugs at a substantially slower rate than the zero-order profile. Placing a matrix tablet in a breakdown media causes rapid drug release from the tablet's surface layer. Tablets lose their medication content over time, requiring water molecules to travel via long, convoluted routes to access the residual medicine in the deeper layers.

POLYMERS USED IN MATRIX TABLET [22]

- *Hydrogels:* Polyhydroxyethylmethylacrylate (PHEMA), cross-linked polyvinyl alcohol (PVA), cross-linked polyvinyl pyrrolidone (PVP), polyethylene oxide (PEO), Polyacrylamide (PA).
- *Soluble Polymers:* Polyethyleneglycol (PEG), polyvinyl alcohol (PVA), polyvinylpyrrolidone (PVP), hydroxypropyl methyl cellulose (HPMC).
- *Biodegradable Polymers:* Polylactic acid (PLA), polyglycolic acid (PGA), polycaprolactone (PCL), polyanhydrides, polyorthoesters.
- *Non-Biodegradable Polymers:* Polyethylene vinyl acetate (PVA), polydimethylsiloxane (PDS), polyether urethane (PEU), polyvinyl chloride (PVC), cellulose acetate (CA), ethyl cellulose (EC).

KINETICS OF DRUG RELEASE [23–24]

Zero Order Kinetics

Drug dissolution from pharmaceutical dosage form that does not disaggregate and drug release in a slow manner represented by:

$$W_0 – W_t = K_0t,$$

where W_0 = Initial amount of drug concentration in solution. Wt = Amount of drug release dissolved in time t. K_0t = Zero order rate constant.

A linear plot of cumulative drug release over time indicates zero-order kinetics, with a slope equal to Ko. This approach provides an optimal release profile for long-lasting pharmacological effects.

FIRST-ORDER KINETICS

Release of Drug Expressing in This Model

$$\text{Log } Q_t = \text{Log } Q_o + K_1t/2.303.$$

Q_t = Amount of drug release in time t. Q_0 = Initial amount of drug in solution. K1t = First order release rate constant.

Plotting data as log cumulative% medication remaining vs. time shows a straight line, demonstrating first-order kinetics. The constant K can be calculated by multiplying slope values.

Drug Release from Matrix [25]

Once the bathing solution is distributed, the medication across the outer layer, it diffuses out of the matrix. As the solid medication and bathing fluid react, the interface follows the interior's course. To regulate diffusion in this system, the speed at which drug particles dissolve inside the matrix needs to be greater than the rate at which dissolved drug departs the matrix. The theoretical framework used to define this system has the following assumptions:

a) A pseudo-steady condition is maintained throughout drug release.
b) The drug particles' diameter is smaller than the typical diffusion distance across the matrix.
c) The bathing solution always maintains sink conditions.

EVALUATION OF MATRIX TABLET

Pre-Compression Characterization [26]

- *Angle of Repose:* Angle of Repose is defined as the maximum angle possible between the surface of a pile of powder and a horizontal plane. The angle of repose was calculated by substituting the values of the base radius "r" and pile height "h" in the following equation: Tan = h/r, where h = Pile Height, r = Radius of Pile.
- *Tapped Density:* A measured amount of granular powder can be assessed by manually tapping or using other methods in a calibrated measuring cylinder. Tapped density was calculated using the following formula:

  Tapped Density = Weight of samples in grams/Volume occupied by the sample.

- *Carr's Index:* Bulk and tapped density determinations provide an important metric of percent compressibility, known as Carr's index I. This is calculated using the following equation:

  Compressibility Index = 1 – (Bulk Density/Tapped Density).

- *Hausner's Ratio:* Hausner's ratio predicts powder flow parameters by considering interparticle friction.

  Hausner ratio = Tapped Density/Bulk Density.

Post Compression Characterization [27]

- *Hardness:* Tablets' hardness determines their resistance to fracture during storage, transportation, and handling before use. Tablet hardness was evaluated using. A Monsanto hardness tester but can also be measured with Pfizer and Strong cob testers. Hardness was measured in kg/cm^2b.
- *Thickness:* Tablet thickness and diameter were critical for ensuring tablet size uniformity. Thickness and diameter were measured using a micrometer screw.
- *Friability:* A Roche friabilator was used to evaluate friability, which serves to estimate dosage strength. After getting precisely weighed, twenty tablets were put in a rotating tumble machine that operated at 25 rpm, dropping the tablets six inches each time. The tablets were reweighed after four minutes to determine the weight reduction % (Table 3).
  % loss = Initial weight of tablets – Final weight of tablets/Initial weight of tablets × 100.

Table 3. Specifications for tablets as per Pharmacopoeia of India.

S. N.	Average Weight of Tablet	% Deviation
1.	80 mg or less	7
2.	More than 80 mg but less than 250 mg	7.5
3.	250 mg or more	5

- *Uniformity of Weight:* Weigh 20 tablets at random to determine their average weight. There are just two tablets that differ from average in weight more than the permitted quantity, and none that do so more than twice.
- *In-Vitro Dissolution Studies:* Using a USP dissolution device, the drug release performance of matrix tablets has been studied in vitro. A dissolution flask usually contains one matrix tablet and 900 ml of media. A continuous temperature bath maintains the flask at 37º ± 0.5ºC.

CONCLUSIONS

This article focuses on the formulation, advantages, and downsides of sustained-release matrix tablets, as well as the polymers employed in their creation. Matrix tablets can improve patient compliance and induce targeted treatment responses. Issues with standard dose formulations. The cost effectiveness and once-daily dosing are plus points, as well as other bonuses. Hence, sustained-release matrix tablets move toward the dosage form design that has been optimized.

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