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COMPREHENSIVE REVIEW ON SUSTAIN RELEASE MATRIX TABLET AND APPLICATIONS

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ABSTRACT

Sustained-release matrix tablets represent a pivotal advancement in drug delivery systems, offering a controlled and prolonged release of active pharmaceutical ingredients (APIs). This technology aims to enhance therapeutic efficacy, minimize side effects, and improve patient compliance by maintaining consistent plasma drug levels over an extended period. The matrix system, often composed of hydrophilic or hydrophobic polymers, governs the release kinetics through mechanisms such as diffusion, erosion, or a combination of both. This paper explores the formulation strategies, types of polymers used, and the physicochemical principles underlying sustain release matrix tablets. It also reviews the critical factors influencing drug release rates, including polymer concentration and drug solubility. Additionally, the paper examines the advantages and potential limitations of these systems, alongside recent advancements and future perspectives in the field. Through comprehensive analysis, this study aims to provide insights into optimizing sustain release matrix tablets for improved therapeutic outcomes.

KEYWORDS: Sustain Release, Matrix Tablet, Polymers, Frequency of dosing.

INTRODUCTION[1,2]

Sustained release matrix tablets represent a significant advancement in pharmaceutical drug delivery systems, designed to enhance therapeutic efficacy while minimizing side effects. These dosage forms are engineered to release active ingredients at a controlled rate, allowing for prolonged therapeutic effects and improved patient compliance. By utilizing various polymers, such as hydrophilic and hydrophobic materials, the matrix structure effectively regulates the diffusion of the drug, ensuring a steady concentration in the bloodstream over extended periods. The formulation of these tablets typically involves techniques such as wet granulation or direct compression, which embed the drug within a matrix of excipients. This design not only prolongs the release of the drug but also reduces the frequency of dosing, which is particularly beneficial for chronic conditions requiring consistent medication levels. As a result, sustained release matrix tablets have become integral in managing diseases like diabetes and hypertension, where maintaining stable drug concentrations is crucial. Furthermore, the development of sustained release systems addresses challenges associated with conventional dosage forms, including fluctuations in drug levels that can lead to adverse effects or reduced efficacy. By providing a more predictable pharmacokinetic profile, these formulations enhance overall treatment outcomes and patient adherence to prescribed regimens. As research continues to evolve in this field, sustained release matrix tablets are poised to play an increasingly vital role in modern therapeutics.

PERORAL SUSTAINED RELEASE FORMULATION

Peroral sustained release formulations are defined as formulations from which the drug release is controlled over a certain period of time. They are intended for administration via the oral route. Terms such as controlled-release, prolonged-action, repeat action.

THE RATIONAL FOR DEVELOPING SUSTAIN RELEASE[3]

1. Enhanced Bioavailability
2. Stable Drug Levels
3. Improved Patient Compliance
4. Targeted Delivery
5. Economic Benefits
6. Innovation and Market Advantage

Drug Delivery Systems

Drug delivery systems are classified into two types.[4]

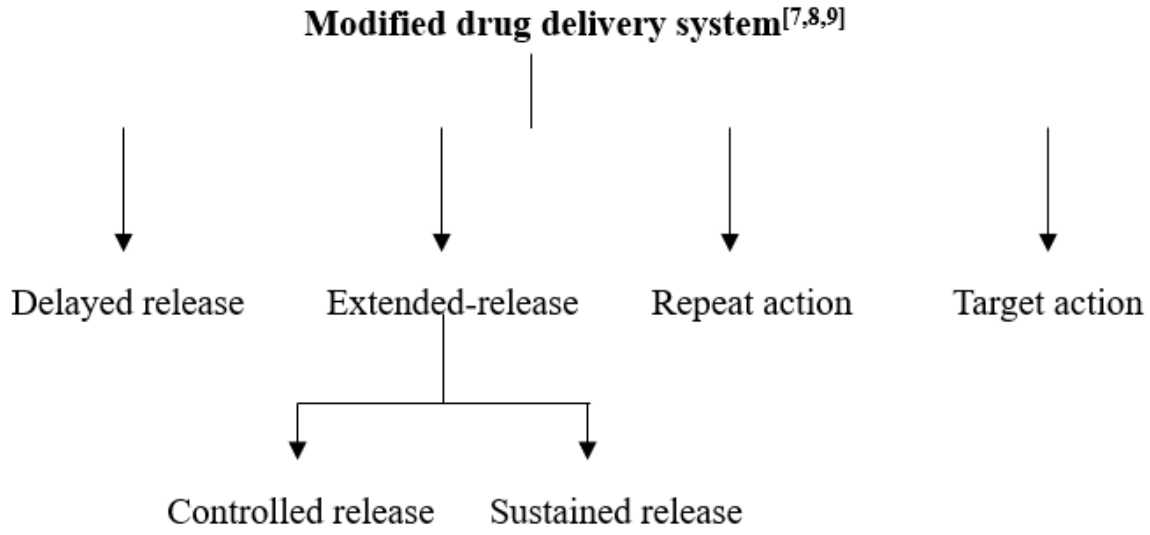
1. Conventional drug delivery system
2. Modified drug delivery system

1. Conventional drug delivery system

For the majority of drugs, conventional drug delivery works well; however, certain drugs have poor solubility issues, a restricted therapeutic window, or unstable or dangerous qualities. Continuous therapeutic agent administration is the ideal technique for maintaining stable plasma levels. This continuous medication delivery can be achieved using a controlled or sustained drug delivery system, as seen in figure 1. These methods of administration offer several advantages over traditional systems, such as improved efficacy, reduced toxicity, and better patient comfort.[5]

2. Modified drug delivery system

Dosage forms can be made to change how the medicine is released over time, for an extended length of time, or to a particular target within the body. Changes in drug release are usually intended to improve the safety and efficacy of the drug, as well as the therapeutic outcome of drug therapy, patient compliance, and administration convenience.[6]



Delayed release: These dose regimens use one or more immediate release units combined into a single dosage form to deliver intermittently.

Extended release: Pharmaceutical dosage forms that need a two-fold reduction in dosing frequency and release the medication at a predetermined rate more slowly than usual.

Repeat action: Two single doses of medication, one for immediate release and one for delayed release, are typically included in these dosage forms.

Target action: Drug release that intends to isolate or concentrate a medication in a particular tissue, body portion, or location for drug action or absorption.

Controlled release: The administration of medication at a rate or location determined by the patient's condition or physiological needs over a predetermined amount of time is known as controlled drug delivery.

Sustained release

Sustained drug delivery may provide an immediate dose required for the normal therapeutic response, followed by the gradual release of drug in amounts sufficient to maintain the therapeutic response for a specified period time usually 8-12 hours. The basic goal of therapy is to achieve steady state blood level that is therapeutically effective and non-toxic for an extended period of time. Sustained release implies slow release of the drug over a time period. It may or may not be controlled release.

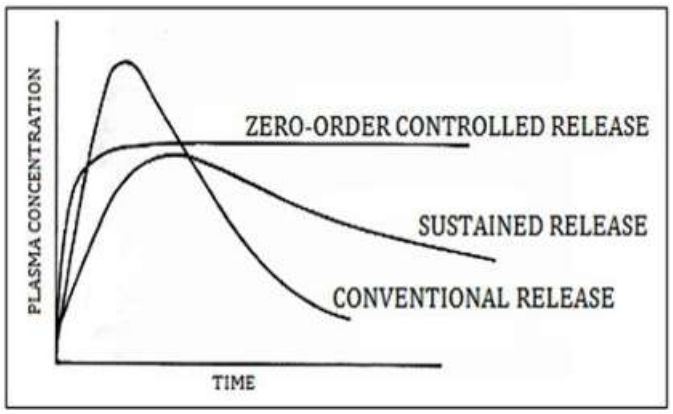


Figure 1: Plasma drug concentration profile for conventional release, a sustained release and zero order controlled release

ADVANTAGES[10,11,12]

1. **Enhanced Therapeutic Effect**: By providing a controlled release of the drug, sustained release matrix tablets can optimize therapeutic outcomes, ensuring that the drug remains within its effective concentration range for extended periods.

2. **Reduced Fluctuations in Drug Levels**: These tablets maintain more stable plasma drug concentrations, minimizing peaks and troughs associated with immediate-release forms. This steady release helps prevent breakthrough symptoms in chronic conditions.
3. **Improved Patient Compliance**: By minimizing the frequency of dosing, sustained release matrix tablets enhance the overall patient experience. Patients often prefer formulations that require fewer doses, which can lead to better adherence and satisfaction with their treatment. This is especially important for geriatric patients or those with chronic illnesses who may find it challenging to manage multiple medications.
4. **Reduced Dosing Frequency:** Patients can benefit from a decreased number of doses required throughout the day. This is particularly advantageous for individuals who may struggle with strict medication schedules, as it simplifies adherence to treatment regimens. For instance, instead of taking medication multiple times a day, patients may only need to take it once daily, improving compliance significantly.
5. **Consistent Therapeutic Levels:** These tablets help maintain consistent plasma drug levels, which can improve therapeutic efficacy and reduce side effects associated with peak concentrations of medication. This stability is crucial for preventing fluctuations that could lead to breakthrough symptoms or adverse effects.

DISADVANTAGES[13]

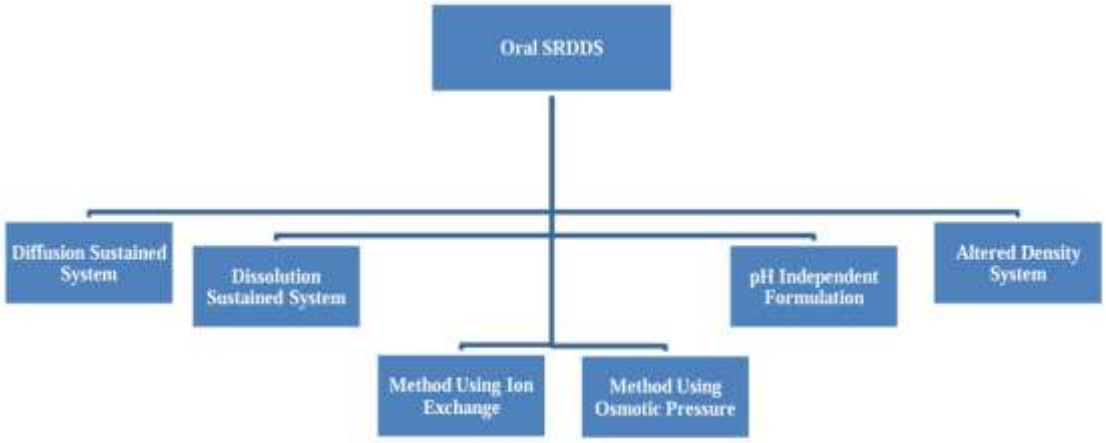
1. **Limited Flexibility in Dosing:** Sustained release formulations often lack flexibility when it comes to adjusting dosages. If a patient requires a dose increase or decrease, it may necessitate switching to a different formulation, which can be inconvenient and potentially lead to treatment delays.
2. **Risk of Overdose and Underdose**: There is a significant risk of overdose if the tablets are not taken as directed. For instance, if a tablet is crushed or chewed, it can lead to a rapid release of the drug, resulting in an overdose. Conversely, missing doses or taking them at incorrect times can result in underdosing, leading to suboptimal therapeutic outcomes.
3. **Difficulty in Dose Adjustments**: Making precise dose adjustments with sustained release tablets can be challenging due to their controlled release mechanisms. This can complicate treatment for patients whose conditions require frequent adjustments based on their response to therapy.
4. **Cost Considerations**: Sustained release matrix tablets typically have higher initial costs compared to conventional dosage forms. While they may reduce overall treatment costs

due to less frequent dosing, the upfront expense can be a barrier for some patients and healthcare systems.

Ideal properties of the drug suitable for SRDDS[14]

1. Drugs with short half-lives (2-4 hrs.) are excellent candidates to be formulated into SR dosage forms.
2. Drugs that have short half-lives (2-4 hrs) are ideal drug candidate for formulation into SR dosage forms
3. The dose of drug should not be less than 0.5gm and maximum dose of drug for designing SRDDS is 1.0 gm

FORMULATION OF SRDDS[15,16,17,18]



1. Diffusion Sustain System

Diffusion is the mechanism by which drug molecules move from a region of higher concentration to one of lower concentration. The amount of medicine that will pass through a membrane in the direction of decreasing concentration is determined by Fick's law.

Reservoir type

A polymeric substance that is insoluble in water envelops the drug's core in this arrangement. The medication will separate into the membrane and exchange the tablet or particle with the surrounding fluid. More medication will mix with the surrounding media, diffuse to the periphery, and enter the polymer. The diffusion process is responsible for the drug's release. Which as shown in figure 2.

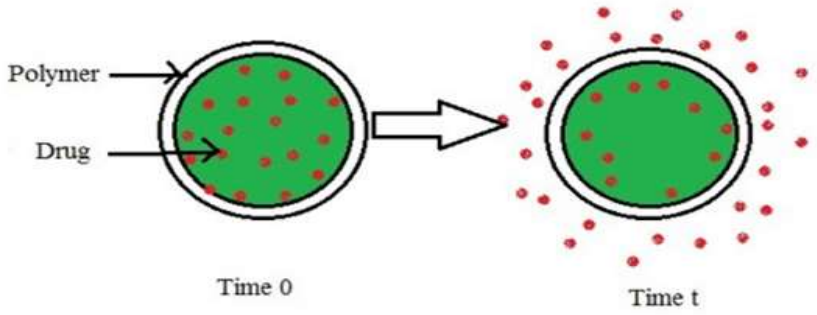


Figure 2: Diagrammatic representation of Diffusion Type Reservoir System.

Fick's first law of diffusion describes the diffusion process,

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

Where,

J = flux of the drug across the membrane

D = diffusion coefficient

dc/dx = change in concentration c with distance x

Matrix Type

A solid drug is dispersed across an insoluble matrix, and the rate of drug release is typically determined by the rates of solid dissolution and drug diffusion. According to this hypothesis, the drug initially dissolves in the bath solution-exposed outer layer before diffusing out of the matrix as shown in figure 3.

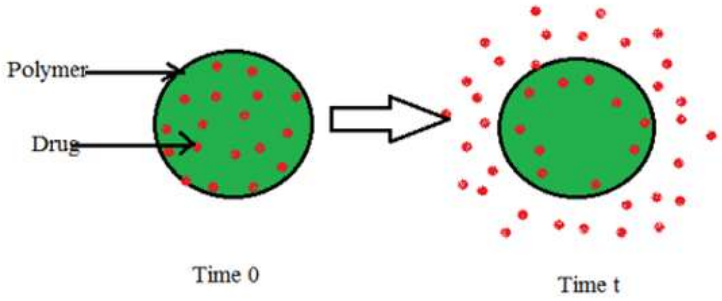


Figure 3: Diagrammatic representation of diffusion sustained drug release: matrix system.

The following equation describe the rate of release of drug dispersed in an inert matrix system have been derived by Higuchi,

$$DQ/dt = (DAC_s/2t)^{1/2}$$

Where,

A is the total amount of drug in a device,

D is the diffusion coefficient of the drug in the polymer,

Cs is the solubility of drug in the polymer,

t is time.

2. Dissolution sustained systems

The dissolution-maintained system automatically sustains slow-dissolving medicines. For pharmaceuticals with high water solubility, salts or derivatives can be formed to speed up the process. These procedures are commonly used to manufacture enteric-coated dosage forms. Until the medication reaches the colon's higher pH, it cannot be released in its dosage form. The Noyes-Whitney equation describes the dissolution process at steady state.

$$dc/dt = KA(CS-C) = D/h$$

Were,

dc/dt = dissolution rate

K = diffusion co-efficient

A = surface area of dissolving solid

Cs = saturation solubility of the solid

C = concentration of solute in bulk solution

H = thickness of diffusion layer

ENCAPSULATION TYPE

These methods frequently involve applying a material that takes a long time to dissolve to individual drug particles. The coated particles can be placed within capsules or instantly compressed into tablets to produce spansule items. Since the amount of time required for the coat to dissolve depends on its thickness and water solubility, a broad or narrow range of coated particles with varying thicknesses can be utilized to produce sustained activity.

MATRIX TYPE

These processes involve compressing the drug with a carrier that progressively dissolves to form a tablet. Here, the rate at which the medication becomes available is controlled by how quickly the dissolving fluid penetrates the matrix. The porosity of the tablet matrix, the presence of hydrophobic additives, and the granule surface wettability can all have an impact on this.

3. Ion exchange resin-drug complexes

It is predicated on the creation of a drug-resin complex that happens when ionic resins and ionic solution come into contact. The overabundance of Na+ and Cl-in the gastrointestinal system causes the medication from this complex to be exchanged and released. This technique typically uses an insoluble cross-linked polymer resin component. On a polymer chain, they have a salt-forming function group in a repeating position.

4. Osmotically controlled system:

This device consists of a tablet containing a water-soluble osmotically active drug that was mixed with osmotically active diluents using triacetate. When a drug is kept in water, a precise hole forms in the barrier that allows the drug to pass through due to an osmotic pressure differential across the membrane. There are two kinds of osmotically sustained systems:

Type A has a drug-containing osmotic core.

The medicine is contained in Type B's flexible bag with an osmotic core environment.

5. pH independent formulations

A basic or acidic medication is mixed with one or more buffering agents, then the mixture is coated with GI fluid permeable film-forming polymer after being granulated with the appropriate pharmaceutical excipients. This mixture is referred to as buffered controlled release. As GI fluid passes past the membrane, the buffering agent brings the fluid's pH down to a suitable, steady level, causing the rate of drug release to remain constant.

6. Altered density formulations

If all contains of dosage form is not released in GI tract then it has a limited use. To this end, various approaches have been developed to prolong the residence time of drug delivery system in the gastrointestinal tract.

High Density Approach

With this method, the pellets' density should be at least 1-4 gm/cm3, which is greater than the stomach's typical content. The medicine can be coated on a heavy core or combined with heavy inert materials as zinc oxide, titanium dioxide, barium sulphate, and iron powder to create such a formulation.

Low density approach

Globular shells which have density lower than that of gastric fluid used as a carrier of drug for sustained release purpose polystyle, pop rice and popcorn are all use as carriers the surface of these empty shell is undercoated with sugar or with polymeric material such as methacrylic polymer and cellulose acetate phthalate. The undercoated shell is then coated by mixture of drug with polymer such as ethyl cellulose and Hydroxy propyl cellulose. Thus, the final product floats on the gastric fluid for a prolonged period, while slow releasing drug.

Factor affecting sustained release drug delivery system.[19,20,21,22,23,24]

Physicochemical factors

a. Dose Size

A single dose of 0.5-1.0 g is often the maximum for traditional dosing. This applies to long-acting drug compositions. When providing high doses of a medication with restricted therapeutic range, it's important to consider the margin of safety.

b. Ionization, pKa and aqueous solubility

A large number of drugs contain mild acids or bases. Because unaltered drugs preferentially permeate lipid membranes, the pKa of the molecule and its absorptive environment are crucial. Drug solubility in aqueous fluids is crucial for diffusion or dissolution-based delivery systems. The majority of the medication enters the small intestine in solid form, causing its solubility to fluctuate significantly during release. Sustained release medication formulations must have a solubility of less than 0.1 mg/ml, according to studies.

c. Partition coefficient

As they are frequently lipid soluble, compounds having a high partition coefficient have very poor aqueous solubility. Furthermore, these substances typically stay in the body for extended periods of time because they can localize in the lipid membranes of cells. This implies that once the medicine is delivered, its solubility may alter by several orders of magnitude. Reports state that a medicine manufactured in a sustained release system must have a solubility of less than 0.1 mg/ml.

$$K=C_O/C_w$$

Where,

Co = Equilibrium concentration of all forms of the drug e.g. ionized and unionized in an organic phase at equilibrium.

Cw = Equilibrium concentration of all forms in aqueous phase.

d. Molecular size and diffusivity

In many sustained-release systems, drugs must diffuse through a rate-controlling membrane or matrix. The molecular size of a drug determines its ability to disperse across membranes (diffusion coefficient) (or molecular weight). The importance of diffusivity is influenced significantly. In polymers, the letter 'D' represents the diffusing species' molecular size.

e. Stability

Both acid-base hydrolysis and enzymatic degradation can occur when drugs are taken orally. Systems that prolong distribution over the entire duration of transit in the GI tract are useful for drugs that are unstable in the stomach. Compounds that are unstable in the small intestine may have lower bioavailability when delivered from a sustaining dosage type.

MATRIX TABLET[25]

Matrix tablets have been the most common form of oral sustained-release pharmaceutical delivery. Matrix tablets work by maintaining a constant plasma drug concentration, sustaining the drug release rate throughout time, and producing therapeutic effects for an extended length of time. To develop a matrix system, the active and inert ingredients are evenly combined and distributed throughout the dosage form. There are several reasons for the matrix system's widespread use, which makes it the most common oral sustained release method. The release from matrix type formulations is governed by Fick's first rule of diffusion. Matrix drug delivery systems distribute the medicament continuously.

Polymers used in matrix tablet.[26]

Table 1: Some Of the Polymers Used in Matrix Tablets

Polymer type	Examples
Soluble polymers	Poly ethylene glycol (PEG), Poly vinyl alcohol (PVA), Hydroxy propyl methyl cellulose (HPMC), Poly vinyl pyrrolidone (PVP).
Biodegradable polymers	Poly lactic acid (PLA), Poly caprolactone (PCL), Poly glycolic acid (PGA), Poly anhydrites, Poly orthoesters.
Non-biodegradable polymers	Poly vinyl chloride (PVC), Poly ethylene vinyl acetate (PVA), Poly dimethyl siloxane (PDS), Cellulose acetate (CA), Ethyl cellulose (EC), Poly ether urethane (PEU).
Mucoadhesive polymers	Sodium carboxy methyl cellulose,

	Polycarbophil, Methyl cellulose, Tragacanth, Poly acrylic acid, Pectin.
Hydrogels	Poly-hydroxyethyl methacrylate Cross-linked (PHEMA), Polyacrylamide (PA), Polyethylene oxide (PEO). poly vinyl alcohol (PVA), Cross-linked poly vinyl pyrrolidone (PVP),
Natural gums	Xanthan gum, Guar gum, Karaya gum, Gum arabica

TYPES OF MATRIX TABLET

A. On the basis of retardant materials used.

Under this category the matrix tablets are further divided into 5 types:

1. Hydrophilic Matrix Tablet[27]

A hydrophilic matrix is commonly utilized to modulate drug release rate. The matrix can be tableted through direct compression of the active component and hydrophilic carriers, or through wet granulation with the drug and matrix materials. The hydrophilic matrix requires water to activate the release mechanism and offers advantages such as easy manufacturing and homogeneity in matrix tablets. To produce a hydrophilic matrix tablet, it is best to use a matrix construction material with quick polymer hydration capabilities. Inadequate polymer hydration rates can lead to early drug diffusion and tablet disintegration due to rapid water penetration. It can be used to create water-soluble drugs. The polymers used in the preparation of hydrophilic matrices are divided into three broad groups as follow:

a) Cellulose Derivatives

Hydroxyethyl cellulose, Hydroxypropymethylcellulose (HPMC) 25,100,4000and15000cps, sodium carboxy methyl cellulose and Methylcellulose 400 and 4000 cps.

b) Non-cellulose natural or Semi-synthetic polymers

Agar-agar, Carob Gum, Alginates, Polysaccharides of mannose and Galactose, Chitosan and Modified starches.

c) Acrylic acid polymer

Carbopol 934 Other hydrophilic materials used for preparation of matrix tablet are Alginic acid, Gelatine and Natural gums.

2. Fat-wax matrix tablet[28]

The medication can be integrated into fat wax granules through spray congealing in air, mix congealing in aqueous media with or without surfactant, and spray-drying. The bulk

congealing method involves allowing a suspension of medication and melted fat wax to solidify before comminution for sustained-release granulations. Granules can be made from a mixture of active substances, waxy materials, and additives by compacting using a roller compactor, heating in a fluidized-bed or steam jacketed blender, or granulating with a waxy material or binder solution.

3. Hydrophobic matrices (Plastic matrix tablet)[29]

Sustained release tablets made from an inert, compressed plastic matrix are extensively utilized. Drug release is typically delayed due to diffusion through the capillary network between compacted polymer particles. Plastic matrix tablets, which embed the active ingredient in a porous skeletal structure, can be easily prepared by compressing the drug with plastic materials that can be comminuted or granulated to the desired particle size. To granulate and compress into pills, the embedding process may be accomplished by,

1. The solid drug which is mixed with plastic powder and kneaded with a solution of the same plastic material or other binding agent in an organic solvent and then granulated.
2. An organic solvent which is used for dissolution of drug in the plastic and granulated upon evaporation of the solvent.
3. Using latex or pseudo latex as granulating fluid which is used to granulate the drug and plastic masses. Example: Polyvinyl chloride, Ethyl cellulose, Cellulose acetate and Polystyrene.

4. Biodegradable Matrix[30]

These are constructed of polymers with unstable backbone connections made up of monomers connected to one another by functional groups. By enzymes produced by neighbouring live cells or by non-enzymatic mechanisms, they are physiologically eroded or dissolved into oligomers and monomers that can be metabolised or ejected. Natural polymers like proteins and polysaccharides, as well as modified natural polymers, are examples, as are synthetic polymers such aliphatic polyesters and polyanhydrides.

5. Mineral Matrices[31]

These kinds of matrices are made of polymers derived from different kinds of seaweed. Example is alginic acid which is a hydrophilic carbohydrate obtained from species of brown seaweeds by the use of dilute alkali.

B. On the basis of porosity of matrix[32]

In this drug molecules diffuse across the matrix and produce sustained release. The matrix is further divided into three types;

1. Macro Porous System

This type of matrix has holes that are between 0.1 and 1m in size, which is greater than diffusant molecule size. This sort of technology allows the medicine to permeate via these pores.

2. Micro Porous System

Permeation of drug molecules occurs through pores of size ranging from 50-200 Å.

3. Non - porous system

These systems have no pores and the molecules diffuse through the network meshes. In this case, only the polymeric phase exists and no pore phase is present.

C. On the basis of the way of matrix preparations

i) Floating matrix system[33]

In this form of matrix system, the matrix has a lower bulk density than the gastric fluid in the stomach. Creating buoyancy in the stomach allows for gradual release of drug molecules from the matrix, increasing gastric residence time and bioavailability of fast release drugs.

ii) pH sensitive matrix system[34]

An enteric coating of the matrix system can shield the medication in this kind of system from the stomach's harsh, acidic environment. Drug molecules that are sensitive to low pH can therefore safely enter the colon and small intestine. In order for drug absorption to take place in the proper region, this matrix technology releases the enteric coated medicine in the GIT at a particular high pH value. This kind of matrix system can employ PH-sensitive polymers like cellulose acetate phthalate or HPMC-phthalate.

iii) Mucoadhesive matrix system[35]

The stomach residence time of medications is greatly extended by mucoadhesive matrix systems, which allow for prolonged retention in the gastrointestinal region for several hours. Bioavailability is enhanced by prolonged stomach retention. With this kind of matrix technology, the drug's release is regulated over time. Gastrointestinal, buccal, ophthalmic, nasal, respiratory, rectal, urethral, and vaginal tissues may be the targeted tissues.

Furthermore, any mucosal tissue in the body can be treated with this kind of matrix system. Swellable hydrophilic polymers are the materials utilized in this system, and they can interact with the glycoproteins present in the gut mucous layer.

METHOD OF PREPARATION OF MATRIX TABLET

1) Direct compression:[36]

This is the simplest and most commonly used method. It involves the following steps:

- **Weighing and Blending:** Active pharmaceutical ingredients (APIs) and excipients (like polymers, diluents, and lubricants) are weighed and mixed to ensure uniform distribution.
- **Compression:** The mixture is compressed into tablets using a tablet press.
- **Polymers Used:** Hydrophilic polymers (e.g., hydroxypropyl methylcellulose (HPMC)) or hydrophobic materials (e.g., ethyl cellulose) are included to control drug release.

2) Wet Granulation:[37]

This method is used for drugs that are not suitable for direct compression:

- **Preparation of Wet Mass:** The drug, polymer, and other excipients are mixed, and a binding solution is added to form a wet mass.
- **Granulation:** The wet mass is passed through a sieve to form granules.
- **Drying:** The granules are dried to remove moisture.
- **Compression:** Dried granules are compressed into tablets.
- **Polymers Used:** Polymers like xanthan gum, Carbopol, or natural gums.

3) Melt granulation:[38]

Meltable compounds act as liquid binding agents during the melt granulation process, In this process

- **Mixing:** Drug and excipients are mixed with a meltable binder (e.g., polyethylene glycol, waxes).
- **Heating:** The mixture is heated until the binder melts, forming granules
- **Cooling and Compression:** The granules are cooled, sieved, and compressed into tablets.

4) The Sintering Method:[39]

Sintering is commonly used when matrix tablets need to exhibit prolonged or controlled drug release characteristics. It involves the following steps

1. **Preparation of Tablet Blend**

- Active pharmaceutical ingredients (APIs) are blended with release-modifying excipients, fillers, and lubricants.
- Polymers such as hydrophilic (e.g., hydroxypropyl methylcellulose) or hydrophobic (e.g., ethyl cellulose, waxes) materials are often included to form the matrix.

2. Compression of Tablets

- The blended mixture is compressed into tablets using a tablet press.
- Tablets may be prepared with a standard immediate-release formulation as a precursor to sintering.

3. Sintering Process

- **Heat Treatment:** The compressed tablets are subjected to a controlled heating process below the melting point of the drug and excipients.
- **Sintering Medium:** This can be done in air, under vacuum, or in an inert gas atmosphere depending on the sensitivity of the components.
- **Temperature and Duration:** The sintering temperature and time depend on the formulation composition and desired release profile.

4. Cooling and Storage

- After the sintering process, the tablets are cooled to room temperature.
- The sintered tablets are stored in a controlled environment to maintain stability.

CONCLUSION

To sum up, the sustained-release matrix tablet presents a viable method for regulated medication administration, improving both patient adherence and therapeutic effectiveness. These technologies guarantee sustained and reliable medication release by employing sophisticated polymer matrices and refining formulation parameters. This lowers negative effects related to peak plasma levels in addition to lowering the frequency of dose. Because of their adaptability, sustained-release tablets can be used with a variety of medications, opening the door for creative pharmaceutical technology solutions. These systems will be further refined by upcoming developments in material science and formulation techniques, expanding their applicability and enhancing patient outcomes.

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