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An Innovative Formulation Development Approach of Sustained Release Matrix Tablet: A Review

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Abstract

This review delves about the various manufacturing process/ method of the sustained release matrix tablet & the methods are direct compression, wet granulation, dry granulation, foam granulation, freeze granulation, nanosponge, sintering method, 3D Printing. These all method possesses distinctive traits & unique benefits. The choice of process depends upon the specific formulation, desired tablet characteristic and production scale**.** In these methods, the solid medicaments are distributed throughout the porous matrix formed by the polymer which controls the medicament releasing & there is a presence of a novel strategy for prolonging drug release is the disintegration-controlled matrix, which maintains release for up to 24 hours by regulating the tablets breakdown rate. This review also discusses about the formulation of sustained release matrix tablet by using Quality by Design (QbD) & their dissolution patterns is indirectly detected by using the AI tool.

Keywords: Sintering, Nano sponge, 3-D Printing, DCMT (Disintegration Controlled Matrix Tablet), Sustained-Release, Artificial intelligence.

1. INTRODUCTION:[1,4]

A homogenous mixture consists of 1 or 2 drugs & a viscosities (water-loving polymers) is termed a matrix, which can reduce at least double the drug administration rate contrasted with immediate release dosage form is called as sustained release matrix tablet.[4] Sustained release matrix tablets are the best sustained action medications & can accept tremendous drug doses, especially for very water-soluble drugs & drugs with shorter half-life. By sustained release medication steady level of plasma drug concentration is maintained which eliminates the requirement for night-time dosing, benefiting both the patient & the caregiver.[1]

1.1. Advantages:[2]

1. **Improve Bioavailability -** drugs which undergoes extensive first pass metabolism, which can enhance bioavailability by sustained release formulation by releasing the drug gradually.
2. **Enhance Therapeutic efficacy-** for prolonged duration, the therapeutic drug concentration in the bloodstream is maintained by a sustained-release tablet, which enhances the therapeutic effect.

1.2. Disadvantages:[1,3]

1. **Drug vs Time –** The drug liberated from the matrix relatively quick at first but after time progress, the release rate steadily decreases.[1]
2. **Poor iviv correlation-** In sustained release matrix tablet, the drug liberated & absorption are not able to predict clearly in human body & laboratory.[3]

1.3. Ideal drug properties:

1. **Molecular weight:** It should be <1000 Da.
2. **Water Solubility:** It should be >0.1 mg/ml for effective dissolution & absorption over the pH 1-7.8.
3. **Partition coefficient:** High Partition coefficient is required.
4. **Absolute bioavailability:** It should be 75% or higher.
5. **Dose size:** It range between 0.5-1.0g per tablet.
6. **Elimination half-life:** It should be 2-8 hours.
7. **Total clearance:** These doses doesn't influences total clearance.
8. **Therapeutic index:** Drug should have wide therapeutic index.
9. **Absorbability:** Absorption of drug are not to be affected by pH & catalyst.
10. Drug should have low therapeutical concentration & smaller V_d & wants to know about eliminate rate constant of the design.

1.4. Drug candidates not suitable for sustained release dosage forms:[23]

1. **Riboflavin & ferrous salt –** In the lower intestine the absorption isn't well.
2. **Penicillin G –** It has shorter biological half-life (<1 hour).
3. **Phenytoin –** It has longer biological half-life.
4. **Sulphonamides-** Large dosage (> 1g) is required.
5. **Digitoxin –** It has low therapeutics indices & also have cumulative action & undesirable side effects.

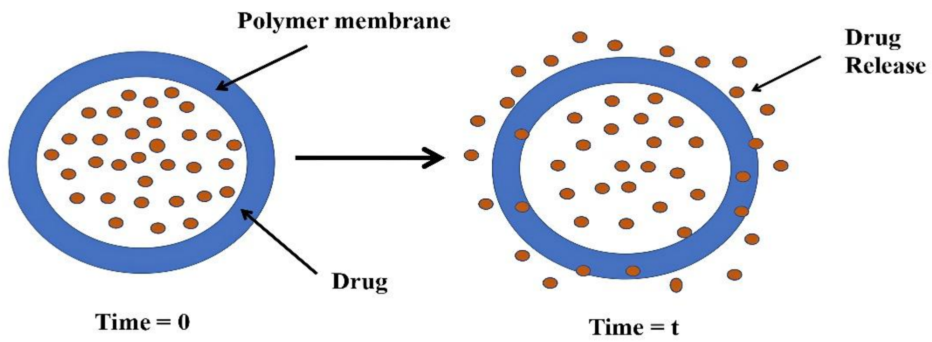

Figure 1: Sustained-release matrix tablet.[2]

2. FORMULATION METHODS OF SUSTAINED RELEASE MATRIX TABLET:

2.1. Direct Compression:[5] This is the most commonly & simplest method for the direct compression of the core drug with polymer.

Steps:

Weighing: API & excipients (polymers, diluents & lubricant) are weighed accurately.

Blending: Uniformly mix the API & excipients to achieve Homogeneity.

Compression: The blend is compressed into tablets & then ejects it.

Advantages:[9]

Moisture & heat sensitive API are more suitable for direct compression.

Direct compression tablet has lower risk of contamination.

Disadvantages:[9]

High dose drugs aren't suitable for direct compression.

In direct compression, an air entrapment may occur leads to capping, breaking, etc.

2.2. Wet granulation:[5] Wet granulation is the process of converting the powder drug into granules with the using of binding agent.

Steps:

Wet mass preparation: Accurately weight & mixing of drug, polymer & other excipients & then add the binding solution to form a wet mass.

Granulation: In order to form granules, the wet mass is allowed to pass through sieve.

Drying: To remove moisture content, the granules are dried.

Compression: The dried granules undergo to compression process to obtain tablet.

Advantages:[9]

Enhances the compactness & uniform distribution of the powder.

In wet granulation, the cross contamination and dust producing is low.

Disadvantages:[9]

During the processing, the materials are lost.

Thermolabile & moisture sensitive drugs are not suitable.

2.3. Dry Granulation:[1] In this method, the powdered drugs are converted into the granules without using the binding agent.

Steps:

Weighing & mixing: Accurately weigh & mix the API, polymer & other excipients to obtain uniform distribution.

Compaction: In compaction, the powder is loaded, after compaction, a slug is obtained.

Milling & Sieving: By milling, the slug is breakdown into smaller granules, the smaller granules are allowed to pass through the sieve to get uniform size particles & remove oversized particle.

Compression: Feed the granules into tablet press.

Advantages:[9]

It consumes less space & machinery, eliminating the requirement for binder liquids, bulky mixers.

Slugging benefits the materials sensitive to heat (or) moisture & promotes faster disintegration.

Disadvantages:[9]

Compared to wet granulation, it produces more dust.

A specialized heavy- duty tablet press is required to create a slug.

2.4. Melt Granulation:[5] In the melt granulation process, the meltable compounds act as liquid binding agents.

Steps:

Mixing: The drug & excipients are mixed with the fusible binder / meltable binder [waxes, polyethylene glycol].

Heating: The mixed substance is allowed to heat, till the binders melt & forms granules.

Cooling: The obtained granules are allowed for cooling process.

Sieving: After cooling, the granules are allowed to pass through the sieve to get a uniform sized particle.

Compression: The uniform sized particles are allowed for compression process into tablet press.

Advantages:[9]

Appropriate for drugs that are unstable in moisture.

Allow adjustment & regulation of drug release.

Disadvantages:[9]

Not suitable for heat sensitive substance.

Binders with low melting points may soften (or) liquify during processing (or) storage.

2.5. Steam Granulation:[17] Steam granulation is a pharmaceutical granulation technique in which the steam replaces water (or) liquid binders.

Steps:

Weighing & Mixing: Accurately weigh & mix the API & other excipients.

Contact stage: Steam is introduced into the powder blend.

Consolidation stage: Steam condenses onto color particles, forming a thin binding liquid film.

Nucleation: Small liquid bridges form between particles.

Growth & consolidation: Particles agglomerate into granules with smoother & rounder shapes.

Drying: The excess heat vaporous the residual moisture from granules & also separate drying unit is prepared.

Compression: By using tablet press, the granules are compressed.

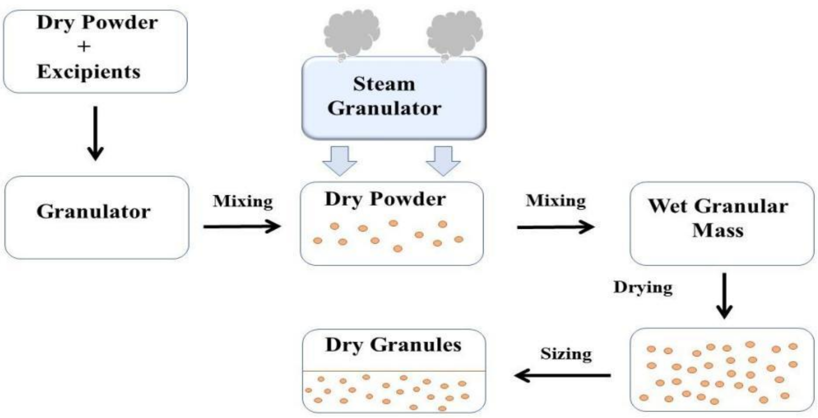

Figure 2: Steam Granulation[9]

Advantages:[10]

It provides high diffusion rate.

It helps to maintain sterility.

Disadvantages:[10]

Incompatible with all binders.

Steamer decomposes quickly.

2.6. Foam Granulation:[17] Foam granulation is a pharmaceutical granulation technique in which the liquid binder delivered as foam instead of spraying.

Steps:

1. **Foam preparation:** By using a foam generator, generate a stable foam from the binder solution (polymer).
2. **Weighing & Mixing:** Accurately weigh & mix the API & other excipients.
3. **Foam addition:** In the powder blend, the binder foam is introduced evenly.
4. **Wetting & Nucleation:** Foam bubbles collapse gradually, releasing binder to wet particles & form initial nuclei.
5. **Granule growth:** Wet nuclei grow by adhesion of more powder particles under mechanical mixing.
6. **Coalescence:** Smaller granules merge into larger cohesive granules.
7. **Drying & Solidification:** Remove moisture to harden granules, ensuring mechanical strength.
8. **Compression:** By using the tablet press, the granules are compressed into tablet.

Advantages:[16]

In foam granulation, spray nozzle is not present.

Foam granulation, increases the process's resilience.

Disadvantages:[16]

In foam granulation, the binder distribution is inconsistent.

In foam granulation, due to various steps validation & control are challenging.

2.7. Freeze Granulation:[17] Freeze granulation is a pharmaceutical granulation technique, in which liquid slurry are rapidly frozen, by spraying into liquid nitrogen & then freeze-dried to form a granule.

Steps:

1. **Weighing & Mixing:** Accurately weigh & mix the API & other excipients.
2. **Liquid Material preparation:** After blending, convert it into slurry/liquid material by using the binder (polymer).
3. **Liquid atomization:** Liquid material is sprayed to form fine droplets by using an atomizer system.
4. **Freezing of droplets:** Atomized droplets are rapidly frozen by direct contact with liquid nitrogen.
5. **Frozen granules:** Frozen granules are collected (or) for further processing (cyclone separation is used).
6. **Freeze drying:** Frozen granules undergo to freeze drying (for moisture removal) to get a dried granule.
7. **Compression:** By using the tablet press, the granules are compressed into tablet.

Advantages:[10]

Freeze granulations have the ability to control the granule density.

Disadvantages:[10]

Freeze granulation, heat sensitive materials are not used.

In freeze granulation, if organic binder is used [Freezing point range from -25 to 10°C].

2.8. Sintering Method:[5]

Steps:

Heat treatment: After compression, the tablet is allowed to controlled heating process & temperature wants to be below the melting points of both drug & excipients.

Sintering method: This heating can be performed in air, vacuum (or) an inert gas atmosphere, depends on material sensitivity.

Temperature & Duration: The specific sintering temperature & duration are determined by the formulation's composition & the targeted drug release characteristics.

Cooling: The tablets are allowed to cool at the room temperature after sintering process.

Storage: The sustained tablets are at the suitable environment for their stability.

Advantages:[8]

Sintering strengthens the mechanical properties of the powder.

Sintering prolongs the control release by elevating temperature.

Disadvantages:[8]

It is a time-consuming process.

Thermal sensitive drugs are not suitable.

2.9. Emulsion solvent diffusion method prepared nanosponge:[7]

Steps:

1. **Preparation of phases:**

   i. **Continuous phase →** Prepared by dissolving the polyvinyl alcohol (PVA) in distilled water.

   ii. **Dispersed phase →** Prepared by dissolving the ethyl cellulose in organic solvent (dichloromethane).

2. **Formation of emulsion:** Disperse phase is added gradually (drop by drop) into the continuous phase. This mixture undergoes to ultrasonication for 30 mins.
3. **Separation:** The obtained resulting nanosponge suspension undergoes to centrifugation process (by using bench top centrifuge) to obtain nanosponge.

4. **Drying:** The obtained nanosponge are dried in a vacuum oven to evaporate the residual solvents.

5. **Storage:** The dried nanosponge are stored in a desiccator to maintain their stability.

Loading of drug into nanosponge:

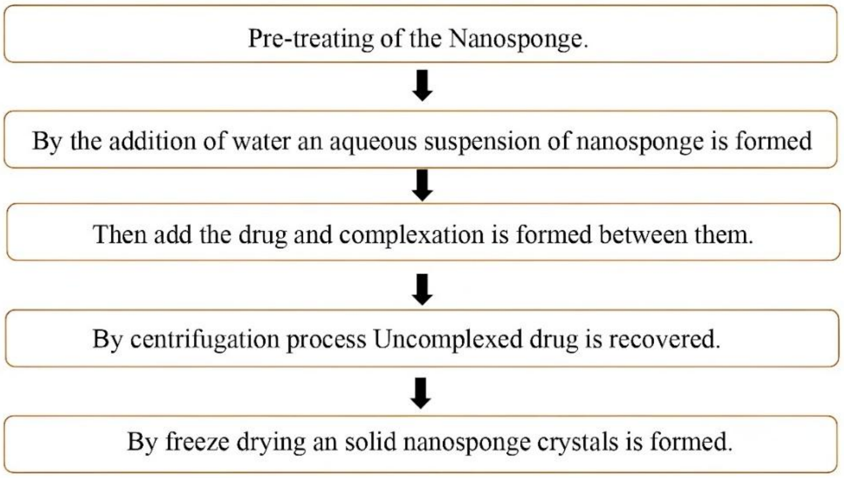

Figure 3: Loading of drug into nanosponge[6]

Advantages of Nanosponge:[6]

Nanosponge enhances the aqueous solubility for weakly water-soluble drugs.

Formulation, stability & flexibility is enhanced.

Disadvantages of Nanosponge:[6]

Dose dumping.

Only smaller molecules are encapsulated, not suitable for larger molecules.

2.10. Hot Melt Extrusion Method:[13] Hot Melt extrusion process is the modern pharmaceutical technique where API is dispersed in polymer matrices under heat & pressure.

Steps:

1. **Weighing & Mixing:** Accurately weigh & mix the API, Polymer & other excipients.
2. **Feeding of Materials:** The blended mixture is introduced into hopper & this ensures accurate design & continuous supply of materials into the extruder barrel.
3. **Material transport:** The rotating screw pushes the materials forward along the barrel length. During transport, the screw provides initial mixing & compression of the formulation.
4. **Melting & Mixing:** Heat from barrel & shear from screw soften the thermoplastic polymers. This creates a molten uniform mass, where drug & excipients are intimately mixed.
5. **Extrusion through the die:** The homogenous molten material is pressurized through the die opening & obtains a film. These film strands can be milled into granules.
6. **Compression:** By using the tablet press, the granules are compressed into tablet.

Advantages:[11]

Hot melt extrusion process enhances the bioavailability of poorly water-soluble drugs.

Disadvantages:[11]

Hot melt extrusion necessitates elevated power input.

Hot melt extrusion process is not suitable for heat sensitive material.

2.11. Spray Drying: [12] It involves transformation of a liquid formulation into a fine powder via accelerated drying using hot air.

Formation of solid lipid microparticles:

1. **Weighing & Mixing:** Accurately weigh & mix the API within the lipid solution.
2. **Spray drying:** Then this solution is sprayed into a hot air stream, instantly evaporating the solvent.
3. **Formation of particles:** After evaporating of the solvent, solid-lipid microparticles are formed.
4. **Mixing with polymer:** The solid-lipid microparticles are mixed with polymer & other excipients.
5. **Compression:** Then this blend is compressed in the tablet press & forms the tablet.

Advantages:[12]

Spray drying supports gentle drying of thermally unstable materials.

Spray drying ensures uniform particle size distribution.

Disadvantages:[15]

Spray dryer instrument requires specialized trained personnel for maintenance and operational purpose.

1.12. Three-Dimensional Printing: [21,22]

Selective Laser Sintering: Selective Laser sintering is a 3D Printing process used in pharmaceuticals to create tablets layer with precise drug release profiles.

Steps:

1. **Powder Bed Preparation:** A thin, even layer of powdered drug & excipients is spread on the build platform.
2. **Preheating:** The Powder bed is gently warmed just below the melting point of the powder to prepare it for laser sintering.
3. **Laser Scanning & Sintering:** A Laser moves over the surface, selectively heating and fusing powder particles in the pattern of that tablet layer.
4. **Lowering and new layer application:** The platform lowers slightly and a new layer of powder is spread over the previous one.
5. **Repeating the Build:** Step 3 and 4 repeats, building the tablet layer by layer until complete.
6. **Cooling and Extraction:** The Printed tablet is cooled slowly to avoid damage, then removed from the unsintered powder.
7. **Post-Processing:** Finished product (tablet) is then undergo to the cleaning, coating.

Advantages:

This technology offers a low-cost manufacturing option.

Disadvantages:

The potential for thermal degradation of the drug due to the intense heat and energy from the laser beam during fabrication.

3. Novel Approach:

3.1. Disintegration Control Matrix Tablet:[14]

In this system, the granules are formed containing the active drug & disintegrant [L-HPC], prepared using approaches like solid dispersion & these granules are coated with insoluble wax, which regulates the drug release. The sustained effect can be achieved either by thickening the wax coating (or) by lowering the quantity of disintegrant used.

Appropriate Drug For DCMT:

Poorly soluble drugs BCS class II, III & IV drugs are available.

Drugs susceptible to re-crystallization after release commonly observed in solid dispersion systems are suitable.

Drugs with stability issues (like photo-degradation) are also suitable.

Merits:

The drugs (or) granules are coated helping to mask unpleasant taste (or) odor.

DCMT entrances drug dissolution & promotes better bioavailability while maintaining normal gastrointestinal transit.

Demerits:

DCMT comprises 3 stages in formulation that are after lengthy, tedious & cost - intensive.

The wax-to-disintegrant ratio must be precise; otherwise, the system may fail to exhibit the intended DCMT release profile.

3.2. Formulation components of the disintegration control matrix tablet:

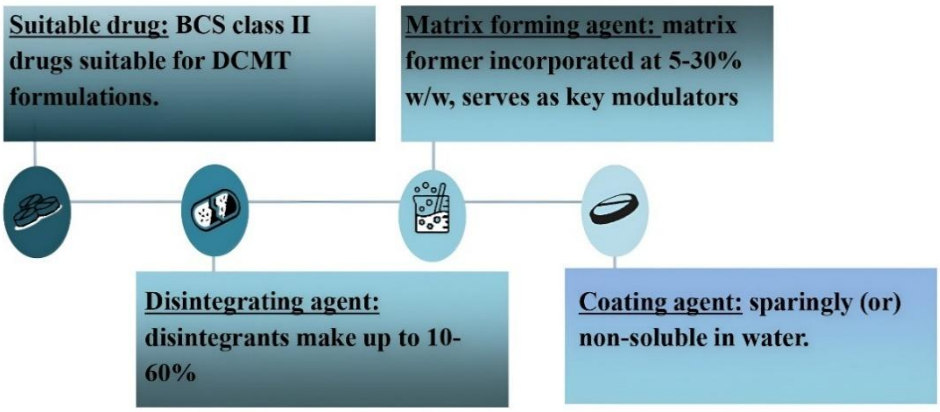

Figure 4: Formulation components of disintegration control matrix tablet[14]

3.3. Preparation of disintegration control matrix tablet:

Solid Dispersion: The Following Steps are taken for the preparation of solid dispersion;

Weighing & Mixing: Accurately weigh & mix the API, disintegrates & other excipients.

Granules Formulation: By Solid dispersion, the granules are formed.

Coating: The granules are layered with coating material.

Compression: After coating, the coated granules are allowed to compress by using tablet press.

Advantages:

The Solid dispersion process promotes better solubilization, faster dissolution & enhance bioavailability of low- solubility compounds.

Disadvantages:

Other than solid dispersion method, the other techniques are used means the stability of the formulation is decreased.

3.4. Mechanism of drug release in DCMT:

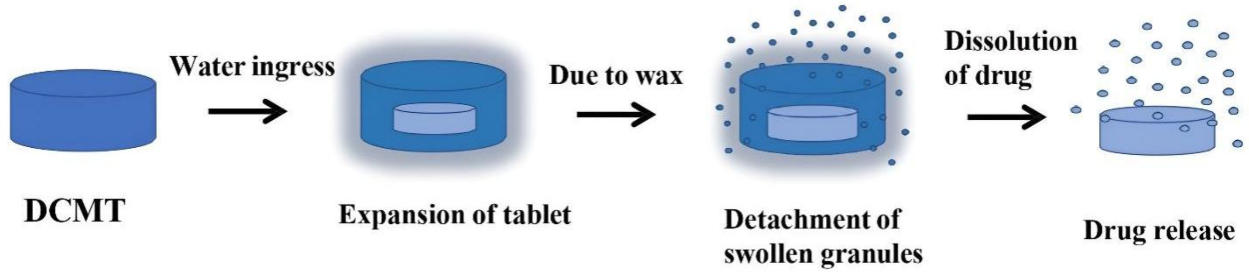

Figure 5: Mechanism of drug release in DCMT[14]

4. AI in Sustained Release Matrix Tablet:[19,20]

1. To Simulate the dissolution patterns of various matrix tablets, both static and dynamic artificial neural networks (ANN) were applied in the formulation design.
2. In this study, Monte Carlo simulations combined with a genetic algorithm optimization approach were utilized to enhance the ANN- based modeling performance.
3. To accurately forecast the dissolution characteristics of water loving and water hating-based matrix tablets with controlled drug release, the researcher employed Elman dynamic neural networks alongside decision tree models.[19]
4. There are two main types of simple RNNs called Elman and Jordan networks. Both have layers for input, hidden processing, delay (which stores past information) and output.
5. The difference is that Elman networks get their delay layer input from the hidden layer, but Jordan networks get it from the output layer. This affects how they remember past information during processing.
6. In contrast to the more commonly implemented multilayer perception and static networks, the Elman network-based modeling effectively simulated drug release behaviors across different water loving and water hating based formulations.[20]
7. Galata and colleagues investigated the prediction of dissolution behavior in water loving matrix sustained released tablets through three artificial intelligence (AI) techniques.
8. In this study, artificial neural network (ANN), an ensemble of regression trees and support vector machines were utilized for data interpretation and dissolution profile forecasting.
9. The modeling database was developed by merging outputs derived from process Analytical Technology and Critical Material Attributes.
10. Results indicated that particle size distribution was a key factor influencing the accuracy of predictions, while ANNs exhibited the highest precision among all the evaluated approaches.[19]

5. Quality By Design in Oral Sustained Release:[21]

QbD represents a regulatory-oriented, science-based framework that focuses on in-depth comprehension of formulation and manufacturing processes

In entails establishing the Quality Target product profile (QTPP), determining Critical Quality Attributes (CQAs) and applying Design of experiments for process and formulation optimization.

Implementation of QbD elements:

Risk Evaluation Techniques.

Process Analytical Technology (PAT) for real-time process monitoring.

Experimental Design methodologies (DOE) for fine-tuning key process variables.

Applications:

The QbD approach has been effectively utilized in designing sustained release matrix formulations, phospholipid-based complexes & gastroretentive dosage forms, ensuring reproducible performance, robust quality, and alignment with regulatory expectations.

6. Conclusion:

This review mainly discusses about the sustained release matrix tablet along with their formulation methods & also explained about various novel methodologies of the sustained release matrix tablet. The most notably, novel approach is disintegration-controlled matrix tablet which regulates tablet breakdown using wax-coated granules & specialized disintegrants to prolong drug release for up to 24 hours & this disintegration-controlled matrices can significantly improve both therapeutical efficacy & patient compliance. Additionally, improved product quality and better control over drug release are guaranteed when innovative formulation techniques are combined with QbD and AI-based methodologies. These developments improve the patient experience and adaptability of sustained release matrix tablets. Therapeutic results will be safer, reliable, and more effective with continued innovation in this field.

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