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Exploring the Potential of Wurster Fluidized Bed Coating in Microparticulate Drug Delivery: A Comprehensive Review

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ABSTRACT

Background: Due to its success in resolving issues associated with conventional treatment, the microparticulate drug delivery system (MDDS) has been considered in the modern era. Spherical particles with a diameter ranging from 1 to 1000 μm are known as microparticles (MPs). MPs can encapsulate both water-soluble and insoluble substances. MDDS has been shown to enhance bioavailability, stability, targeting, and the regulation of drug release (DR) patterns. By lowering drug toxicity and dosage frequency, MPs improve patient compliance and provide comfort and ease of administration. **Objective:** This review comprehensively explores the advantageous integration of MDDS with Wurster coating in diverse industries such as pharmaceuticals, agriculture, and food. The discussion encompasses the preparation techniques of MDDS, the fundamental principles and mechanisms underlying Wurster coating, and the strategic rationale for combining both approaches. Additionally, the review delves into the practical applications of this synergistic strategy in industrial settings while addressing the challenges associated with scale-up. **Conclusion:** By providing a thorough examination, this review elucidates the scope and limitations inherent in integrating MDDS with Wurster coating, offering a clear understanding of this innovative approach.

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1. INTRODUCTION:

On comparing with immediate-release dosage forms, the oral sustained-release (SR) dosage forms offer several advantages, such as the ability to optimize pharmacokinetics, enhance pharmacodynamics, lower dosing frequency, improve compliance, and hence promote overall treatment effectiveness (1). The majority of SR dosage forms, such as coated and matrix tablets or osmotic pump systems; so, are unsuitable for aged people with swallowing difficulties (2), including dysphagia (3). A large number of old people have swallowing trouble (4). Crushing tablets, which are

frequently employed to solve this issue (5), is inappropriate for use with SR tablets due to their interference with their functionality, which can cause dose dumping, unwanted adverse events, and even toxicity (6,7). Liquid dosage forms, including drops, syrups, solutions and suspensions, are suitable for patients with swallowing difficulties (8), but these cannot be easily prepared with an SR profile. Hence, to overcome these barriers, MPs are formulated (9). MDDS entraps solids, liquids, or gases in size ranges of 1- 1000 μm and protects them from the harsh external environment by encasing them in inert polymeric shells (10). They can be delivered to the target organs directly or via a variety of delivery methods, such as intramuscular, intraperitoneal, intra-organ, subcutaneous, and pulmonary. Through gradual diffusion over extended periods of time, this delivery system primarily facilitates the controlled and SR of the enclosed particles. Because of its unique and appealing qualities, such as biocompatibility, target specificity, stability, uniform encapsulation, controlled and SR patterns, and improved compliance that lessen toxicity and dosage frequency, MDDS play a crucial role with a strong

therapeutic impact and is in demand globally in medical technology (11). The preparation techniques of MPs include spray-dried (12) and spray-congealed (13) emulsion solvent evaporation (14) and others. The method of preparation of microparticles narrated is considered very expensive, and there is a problem with industrial scalability of these methods. To resolve this issue, the Wurster fluidized bed (FB) coating technique is commonly utilized in pharmaceutical processes as it provides drug-loaded, discrete MPs that are surrounded by polymer film coatings to provide SR in an industrially scalable manner (15). Hence, the review highlights the fundamentals of MDDS, basic principles and mechanisms of Wurster coating, and the rationale for combining both applications. Finally, the application of MDDS prepared using the Wurster coating technique.

2. Fundamentals of microparticulate drug delivery

2.1. Characteristics of microparticles

A MDDS refers to a type of drug delivery system (DDS) where drugs or therapeutic agents are formulated into small particles, typically in the micrometer range. These microparticles serve as carriers for the drug and are created to manage the release, absorption, and targeting of the therapeutic agent. These systems are utilized to improve drug bioavailability, stability along with therapeutic efficacy (16). "Kramer proposed using albumin microparticles in medication delivery systems in 1974. Microparticles as continuous release carriers were proposed by Java Krishna and Catha in 1997. Haemoglobin has also been reported to be used as a natural biodegradable carrier for medications in Microparticulate delivery." (17).

There are various types of MDDS, including microspheres, microcapsules, nanoparticles, and minitabets. These are microscopic solid or liquid droplets or particles that range in diameter from 0.1 to 200 μm . They are enclosed in walls of natural or synthetic polymer films with various permeability and thickness, which function as a substance to control the release rate (16).

2.2. Benefits of microparticulate drug delivery system

MDDS offers several advantages due to their unique characteristics, such as size and shape, etc. Some of them are mentioned in brief below.

- Drug's targeted delivery, such as inhalation and ocular delivery, is directed by the size of the particles.
- They help in the SR and controlled release (CR) of the entrapped medication and shield the encapsulated drug from the stomach and other external conditions.

- By addressing the solubility of poorly soluble active agents, MDDS improves their solubility profile.
- The direct intratumoral delivery of several anticancer medications demonstrates the function of MDDS as a target-specific delivery system.
- They increase the loaded drug's bioavailability, maximizing therapeutic benefits and reducing adverse effects.
- MDDS improves patient compliance by avoiding repeated drug administration and masking the taste and odor of drugs.
- Additionally, by loading incompatible agents into a single shell and separating them via encapsulation, MDDS helps deliver agents.
- It is simple to implement.
- pH-sensitive MPs are used in gene therapy, vaccines, and transfection.

Despite having many advantages, microparticulate drug delivery system has certain limitations:

- The cost to produce MDDS is much higher than that of the corresponding standard preparations, and achieving high procedural standardization is necessary to ensure formulation reproducibility.
- Since of their small size and large surface area, microparticles tend to aggregate, which makes handling them physically challenging in both liquid and dry forms. Less reproducibility.
- Temperature change, pH, evaporation, solvent addition, agitation may affect the stability of core material.
- More time is required regulatory challenges.
- Variables including the type of polymer, residence duration, and the presence of food affect it.
- When the active ingredient is formulated at different doses, its release kinetics change. Because of polymer degradation, drugs can occasionally be delivered to locations other than the intended ones. (11,17,18).

2.3. Methodologies of preparation of MDDS

The preparation of MDDS involves various techniques to achieve the desired particle size, drug encapsulation, and controlled release properties. Those techniques are enlisted below in Table 1.

A) Physical methods

a. Physico-chemical methods

- Co-acervation
- Solvent Evaporation
- Complex precipitation
- Layer-by-layer adsorption
- Supercritical fluid extraction
- Ionotropic gelation

b. Physico-mechanical methods

- Spray drying
- Spray congealing
- Vacuum encapsulation
- Pan coating
- Electrostatic encapsulation
- Air suspension (Fluidized bed)
- Extrusion
- Multiorifice centrifugal method

B) Chemical methods

- Emulsion polymerization
- In-situ polymerization
- Interfacial polymerization (IFP) (19).

The microparticles are prepared by chemical reaction in chemical methods. In the emulsion polymerization technique, the core material is added to the aqueous polymerization medium along with a suitable emulsifier (20). Then, to this medium, the monomer is added drop by drop. In IFP, the Reactive monomer is used. Generally, multifunctional acid chlorides and multifunctional isocyanates are used. In situ polymerization is the same as the IFP method. This method also forms the shell by polymerizing monomers that are added into the encapsulation reactor. But no reactive agents are added. In

physical methods, polymers are used as a starting material. According to Bungenberg de Jong and Kruyt (1929) and in (1949), this is the partial dissolution of a homogeneous polymer solution into the coacervate phase, which is polymer-rich, and the coacervation medium, which is poor polymer-phase. Originating from the Latin word "acervus," which means "heap," comes the term "coacervation." This was the first reported procedure modified for the commercial manufacturing of microcapsules. There currently exist two ways to coacervate, such as simple processes and complex processes (21). The most popular method is spray drying because it has the advantages of quick production and controlled particle size, shape, and density—all important aspects of drug delivery (22). Due to its quick drying (seconds or milliseconds) and comparatively short heat exposure time, spray-drying technology has recently been successfully used for a variety of heat-sensitive protein medications (23). Among these techniques, Fluidized bed coating has gained more attention in the pharmaceutical industry. It is of three types: top, tangential, and bottom spray (24). The frequently used method is bottom spray, which is also referred as the Wurster process (see following section).

Table 1: Techniques employed for formulation of a microparticulate drug delivery system

Drug	Coating Material	Technique	Results
5-fluorouracil	PLGA, PVA	Emulsion- extraction	Microparticles can sustain the DR over 18 days (25).
Acetazolamide	Eudragit RS, Eudragit RL	Solvent evaporation	CR is achieved with the microspheres without having initial peak levels. As a result, these microsphere formulations may reduce side effects, dosing frequency, and may enhance patient adherence (26).
Acetaminophen	Chitosan	Spray drying	This spray dried microspheres can be used as controlled DD carriers. Particle size of microspheres was 3.8 to 4.2µm, entrapment efficiency was 96.3-98.7%. Smooth surface and spherical microspheres were obtained and followed Fick's law of diffusion (27).
Albendazole	HPMC, PVP, PVA	Spray drying	The obtained microparticles showed enhanced dissolution rate of albendazole (28).
Betaxolol HCL	Eudragit, Montmorillonite	Oil-in-oil emulsion- solvent evaporation	The MP showed less toxicity and also exhibited prolonged retention time and extended duration of action (29).
Curcumin	Ethyl cellulose, Carbopol 934P	Emulsion-solvent evaporation	Free flowing microspheres were obtained. DR follows non-fickian model Due to controlled release of drug from microspheres these mucoadhesive microspheres may be used for both local as well as systemic action in effective H. pylori infection treatment (30).
Dexamethasone	Albumin	Spray drying	This method produces the albumin microspheres with lipophilic drug loading. Size of microspheres was between 2 to 7.8µm and showed 76.6 to 93.7% of entrapment efficiency (31).
Diclofenac sodium	Chitosan, Sod. alginate, Agar	Ionotropic gelation method	Spherical microspheres showed an increased DR rate and controlled DR for prolonged period of time (32).
Furosemide	Sodium alginate	Ionic cross-linking method	Microspheres showed 65% to 93% of entrapment efficiency. By varying different formulation parameters, it was found that the entrapment efficiency and particle size also changed. It showed irregular transport mechanism (33).
Gliclazide	Sod. alginate, Sod. CMC, HPMC, Carbopol 934P	Orifice-ionic gelation	Microcapsules were spherical, discrete, and free flowing. The DR was found to be extended (16 hrs) and hence useful for long term delivery of drug. Its microencapsulation efficiency was 65-80% and showed good mucoadhesion (34).
Glimepiride	Sod. alginate, HPMC	Ionic gelation and Emulsification gel method	good flow properties and encapsulation efficiencies. The DR rate decreased with increased concentration of coating material. Microparticles formulated by emulsification gel technique showed slow-release rate as compared to ionic gelation technique (35).
Ibuprofen	Ethyl cellulose	Solvent evaporation	It showed that production variables affect the size distribution, amount of

			free drug and drug loading. It concluded that the parameters which affects the uncoated drug present on microparticle surface strongly influence the DR from microparticles (36).
Ketoprofen	Polysorbate 80, Carnauba wax	Emulsion congealing	This method produced spherical particles which showed sustained drug release. The formulated microspheres showed 200µm average diameter. The obtained microsphere formulations were showed good flow properties, high drug load (about 50%w/w) and prolonged release of drug (for more than 24 hrs (37).
Metformin	Homolipid Poloxamer 188, Phospholipon 90 H	Melt emulsification	Obtained microparticles were spherical, stable, and smooth surfaced. In-vivo studies for antidiabetic property showed higher reduction of glucose. It gave a new approach for delivery of metformin (38).
Naproxen	Ethyl cellulose	Spray drying	Microparticles obtained had spherical shape and size range of 10-15µm. Zero order release profile was followed by microparticles for skin permeation. It might prove as a potential delivery system with good efficacy (39).
Norfloxacin	Sod. alginate	Ionotropic gelation	Microbeads showed drug entrapment in range of 37.26% to 91.73%. Microbeads showed controlled release of drug. Release of norfloxacin from microbeads was observed to be affected by different concentration of sodium alginate (40).
Ondansetron	Gellan gum	Spray drying	Microspheres were spherical and showed uniform particle size distribution. This gel reduces the rate of ciliary clearance and thus causes prolonged residence time (41).
Propranolol HCL	Bovine serum Albumin, Span 80, Tween 80	Emulsion –internal phase stabilization	1-25µm diameter, showed 9% w/w of encapsulation and better bio adhesion (about 70%). Microspheres showed burst effect initially and then more gradual terminal release. Thus, it showed biphasic release pattern. They showed sustained release form and controlled by diffusion. Microspheres provide steady plasma concentration of propranolol and increased bioavailability (42).
Repaglinide	Chitosan, HPMC, Sod. alginate	Ionotropic gelation	Microparticles had 78.62% to 91.20% of entrapment efficiency and showed fickian and anomalous DR profile. It also showed that with increased concentration of polymer there is decrease in amount of DR (43).
Valsartan	Polysorbate 20, Polysorbate 80	Spray drying	Microparticles entrapped micelles showed enhanced dissolution of valsartan tablet. Obtained tablets showed enhanced dissolution rate irrespective of pH condition. They preserved the integrity and characteristics of encapsulated micelles (16).

3. Hot melt extrusion method (HME)

Extrusion is the process of forcing a material through an orifice or letting it die in a controlled environment to alter its physical characteristics. The primary categories of extrusion equipment are roll, screw, radial screen, and ram extruders. The most significant of these in the pharmaceutical sector are the screw extruders (HME), which continuously transform raw materials into the final form, such as a rod, tube, or film. The feed material is forced forward towards the die by the rotating screws, and as it passes through the barrel wall and develops frictional heat, the material becomes softer. When the feed reaches the screw's end, it is viscous and can be forced through a die or orifice to take on the desired shape (44).

The HME (**Figure 1**) is an established procedure that has been used since the early 1930s for the preparation of various dosage forms, especially solid oral dosage forms. This is a novel modified variation of the extrusion spheronization method. It includes the use of heat and mechanical force to melt and mix several components. In order to create solid spheres or pellets, a drug substance and excipients are first transformed into a molten or semi-molten state and then shaped using the proper tools. This is a continuous, simple, and efficient process that needs fewer processing steps. Since it involves adding

water or another solvent, it does not require a lengthy drying stage, in contrast to the granulation process (45).

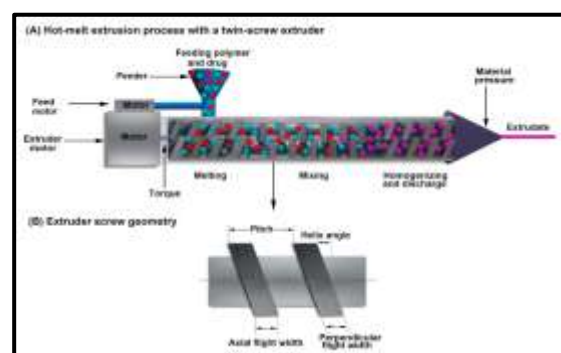


Figure 1: Hot melt extrusion process (46).

Table 2: Advantages and Disadvantages of HME (44).

Advantages	Disadvantages
• Continuous procedure. • More throughput. • No need of solvent. • Enhances solubility also bioavailability of poorly water-soluble drugs. • No need of downstream processing. • Broad uses in pharmaceutical industries.	• Processing thermolabile substances. • Less number of heat stable polymers. • Needs raw materials with higher flow properties. • High energy input. • Protein drugs may be degraded at

• Useful for low compressibility index active pharmaceutical ingredients (APIs). • Thermodynamically stable. • Exposure to oxygen in extrusion channel is limited.	higher temperature.
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3.1. Applications of HME in pharmaceutical industry

It offers many benefits to encapsulating drugs with HME, including the fact that very little or no solvent is needed, which lowers costs. Additionally, it can shield sensitive medications and mask the taste of bitter APIs. Chang *et al.* used the HME technique to encapsulate ascorbic acid (AA) in a glassy carbohydrate matrix (47). Here, they used the HME process to successfully prepare microencapsulated AA using maltodextrin and a combination of gum arabic, trehalose, and maltodextrin. The authors postulated that the selected carbohydrate material's glassy matrices may provide improved barrier qualities to disperse AA and lessen undesirable interactions. Khor *et al.* (48) Using the HME method, microencapsulated quercetin is used to mask taste by adding excipients like carnauba wax and shellac or zein. Carnauba-wax-encapsulated powders demonstrated superior taste-masking effectiveness of all microencapsulated formulations (zein, shellac), as demonstrated by dissolution studies and electronic tongue bitterness analysis. This is explained by the carnauba wax's hydrophobicity and inertness. The aforementioned analysis leads to the conclusion that HME's microencapsulation can be a desirable technique for creating taste-masked products, protecting the medication from the environment, and encasing unstable active ingredients in polymeric or non-polymeric carriers (46). Mehuys *et al.* created a SR system with cylinders of hot-melt extruded ethyl cellulose with an HPMC-Gelucire core. An example of a core-shell microcapsule system made using HME is this one. Furthermore, the drug's solubility had no effect on the mechanism or rate of release (49).

4. Wurster fluidized bed coating: basics and mechanisms

In the chemical, food, and agricultural sectors as well as the pharmaceutical industry, coating is a necessary procedure. There are four primary types of fluidized bed (FB) apparatuses that are currently in use for coating particles: Wurster, rotated bed, spouted bed, and bubbling bed. Top, bottom, and side (tangential) spray systems are distinguished based on the position of the spraying nozzle (50). One of the most adaptable coating techniques frequently employed in the pharmaceutical industry for coating tablets and particles smaller than 1 mm is the Wurster fluid bed coating. Temperature

homogeneity and rapid heat and mass transfer are provided. **Figure 2** depicts the Wurster apparatus's fundamental parts. Wurster (1966) suggested adding a vertical draft tube to the device to produce a circulating flow pattern that would allow for the operation of the device with a significant bed height and small particles. The annulus of the perforated plate has smaller orifices than the tube region (9). The Venturi effect draws the particles into the tube and causes them to travel upward, creating a spout, because of the tube's greater flow velocity compared to the outer bed region. Particles in the tube move upward, passing through the nozzle zone where they are coated in atomized droplets that eventually combine to form a liquid film. Particle velocity is reduced in the apparatus's expansion area, which is usually conical in shape, and solid material is circulated back to the coating zone (51). They then fall back down outside the tube. This circulating flow through the bottom plate is caused by the inlet airflow; higher fluid velocities inside the tube than outside are caused by larger holes in the bottom plate's center (**Figure 3**) (52). This setup is intended to establish separate regions for spraying and drying, reducing the risk of agglomeration (53). The size of the droplets is determined by the atomizer air pressure; they should be small enough to produce a smooth coating but not so small as to increase the chance of them drying out before they are deposited on the particles (50). The time-consuming setup and process optimization of Wurster is its primary drawback. For specific applications like enteric or sustained release formulation, manufacturers currently favor this method. Using a traditional top-spray fluidized bed allows for coloring, odor, or taste masking, with less concern for coating porosity and uniform film thickness. Wurster works less well when processing large tablets because rotating pans are usually utilized for this kind of work (54).

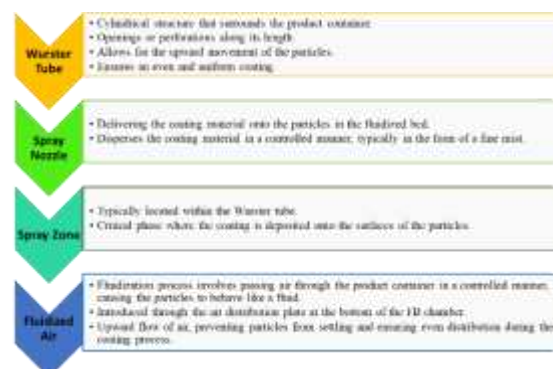


Figure 2: Features of Wurster coater components (Own creation).

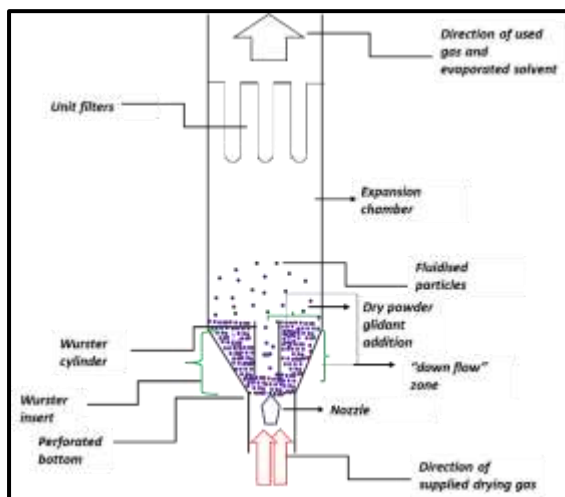


Figure 3: Wurster coating apparatus (Own creation).

4.1. Key Considerations and Advantages:

- **Uniform Coating:** The fluidized bed ensures that the coating material is uniformly applied to the surfaces of the particles.
- **Controlled Release:** The process allows for precise control over the thickness of the coating, influencing the release profile of the core material.
- **Efficiency:** Wurster coating is an efficient process, and the fluidized bed facilitates good contact between the particles and the coating material.
- **Applicability:** It is widely used for coating pharmaceuticals, agrochemicals, food products, and other particulate materials.
- **Adaptability:** The process can be adapted for coating multiparticulate systems of various sizes and shapes (55).

Table 3: Process variables to take into account while Wurster coating

Parameters
Inlet air temperature and humidity
Fluidization air flow rate
Air distributor Position of draft tube
Batch size
Spray rate Position and type of atomization nozzle
Atomization pressure and Inlet temperature of coating medium
Composition and concentration of coating medium

5. Rationale behind combining Wurster coating and microparticles

The rationale behind combining Wurster coating and microparticles lies in the advantages each method offers, and their synergy in achieving specific formulation goals.

- Wurster coating effectively provides a thin, uniform coating on individual microparticles. This is crucial for achieving precise control over the release of the encapsulated material.
- By combining Wurster coating with

microparticles, it is easy to create a system where each microparticle is coated uniformly, offering protection and controlled release.

- This combination allows for tailoring the release profile of the active ingredient, optimizing bioavailability, and ensuring that the therapeutic effect is achieved over a desired duration (9).

The combined use of Wurster coating and microparticles is widely applied in the pharmaceutical industry to develop modified-release dosage formulations, including extended-release tablets or capsules. It is also used in the agricultural and food industries for encapsulating and controlling the release of pesticides, nutrients, or Flavors (56).

5.1. Different types of micro multi particulate systems suitable for widely used proven coating process like Wurster coating

Often utilized aspects of MDDS, microparticles, microspheres, and microcapsules provide both medicinal and technological benefits (Figure 4) (57). The drug is uniformly dispersed, dissolved, or suspended within microspheres, which are matrix systems. In 1997, the first microspheres were created to continuously release medication. Following being approved as a suitable candidate for a continuous and controlled drug release, they have been employed as cutting-edge drug delivery systems (58). Microspheres are small spherical particles ranging in size from 1 to 1000 μm (Figure 5). A microcapsule is made up of a liquid core with a diameter ranging from a few microns to 1 mm, encased in a thin, strong, spherical, semi-permeable polymer membrane (Figure 5). microcapsules with a wall around them so that the reservoir's release can be controlled (59). Numerous studies have demonstrated that these MDDS are appropriate for coating procedures such as Wurster coating. In one study, melt spray congeal (MSC) microsphere coating was observed in real time using three PAT tools (FBRM, Raman, and NIR) mounted on a bench-top Wurster fluid bed (60). Polysiloxane coatings on 500 μm yttria stabilized zirconia (YSZ) microspheres were simulated in another work using Multiphase Flow with Interface Exchange-Discrete Element Modelling (MFiX-DEM) in a spout fluidized bed coater. The Wurster tube's presence improves the particles' distribution and extends their total residence time (61). Additionally, to create SR drug delivery, the hydroxyl propyl methyl cellulose (HPMC) and EC (ethyl cellulose) were used as release retarding polymers in the spray coating (Wurster method) process for producing the diclofenac-loaded microspheres (62). Numerous researchers have attempted in a few studies to prepare prolonged-release microcapsules containing

Diclofenac Sodium (DS) suitable for an oral suspension. The particle size had to be small enough to be easily suspended in an aqueous vehicle to apply the microcapsules to a prolonged-release suspension. Furthermore, the microcapsules needed to contain the maximum amount of DS as possible. However, because DS is highly water-soluble, it was expected that loading a large drug quantity into the tiny microcapsules would make prolonged release challenging. Ichikawa and colleagues investigated the potential of Ion-exchange resin (IER)-DS complexes as building blocks for the Wurster process to create a 100 μ m-sized, highly drug-incorporated microcapsule with extended DR (63). As a short-term controlled release dosage form, Fukumori *et al.* successfully created microcapsules with a soybean lecithin coat using the Wurster process (64).

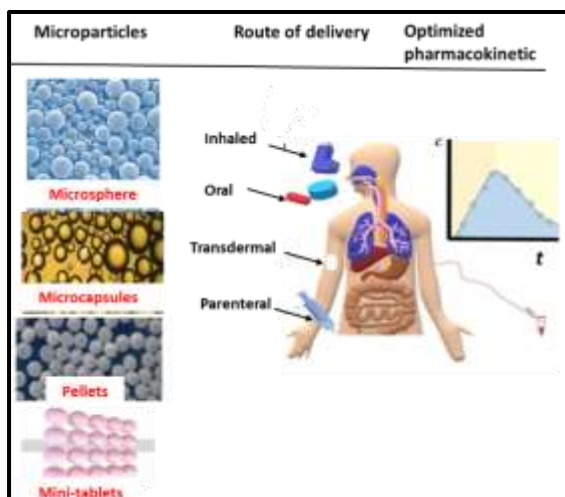


Figure 4: MDDS offering therapeutic and technological advantages (57) (Source+ Own creation).

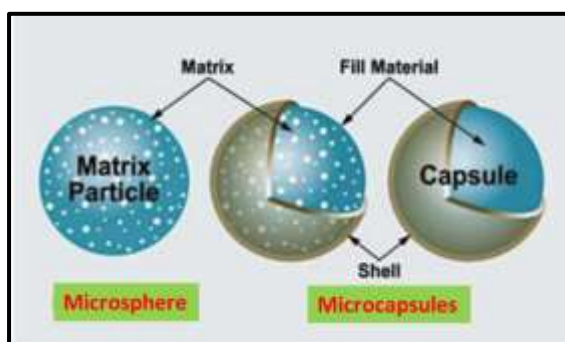


Figure 5 : Microsphere and Microcapsules (65).

Mini-tablets, which have a maximum diameter of 3 mm, are a kind of oral medication that is gaining popularity, particularly among older and paediatric patients. Traditionally, tablets are coated using drum coaters; however, fluidized bed coaters are used for mini-tablets (66). The uniformity of the coating on the mini-tablets produced by using a swirl distributor (SW) or the bottom spray chamber equipped with a traditional Wurster distributor (CW)

(67). The applied coating needs to be the necessary thickness in order for it to function (68).

6. Advances and innovations in Wurster coating technology

Smart coating technologies

Integrating smart or responsive coating materials that can respond to specific stimuli, such as pH or temperature changes, leads to controlled drug release. This innovation allows for more precise drug delivery targeting specific areas in the gastrointestinal tract.

Layer-by-layer coating techniques

Application of layer-by-layer coating, where multiple layers of different materials are sequentially applied to achieve specific functionalities. This approach allows for precise control over the coating composition and properties.

Nanotechnology integration

Integration of nanotechnology into Wurster coating processes for the development of nanocoatings. Nanoparticles or nanocomposites may offer enhanced control over DR and improved bioavailability.

Coating process automation

Advancements in automation and control systems for Wurster coating processes to improve efficiency, reduce variability, and enhance overall process control. Automated systems can lead to better reproducibility in coating thickness and quality.

Continuous manufacturing

The adaptation of Wurster coating to continuous manufacturing processes. Continuous manufacturing is gaining prominence in the pharmaceutical industry for its potential to improve efficiency, reduce costs, and enhance product quality.

Advanced coating materials

Exploration of novel coating materials with improved functionalities, such as polymers that provide not only controlled release but also specific targeting or enhanced stability of the coated particles.

In-line monitoring and quality control

Integration of advanced in-line monitoring and quality control technologies ensures the coating process's consistency and quality. This may involve real-time monitoring techniques like near-infrared spectroscopy or imaging systems.

3D Printing for Coating Design

Exploration of 3D printing techniques in combination with Wurster coating to design intricate

coating patterns or structures for personalized drug delivery (61,69).

7. Applications of Microparticulate Drug Delivery with Wurster Coating

Wurster coating is a process used in pharmaceutical and other industries to coat particles, typically in the micrometer range, with a thin layer of material, including pharmaceuticals, agrochemicals, and food

products. They are used for Uniform coating, controlled release, taste and odor masking, encapsulation of active ingredients, and improved bioavailability. This versatility makes it a valuable technique in various industries. The industrial-scale applications of MDDS coating using a Wurster coater are mentioned below (Table 4).

Table 4: Use of Wurster coating MDDS for various purposes.

MDDS	Materials	Major findings
Diacerein loaded microspheres	HPMC and EC	Sustained release drug delivery (62).
Ibuprofen loaded and unloaded alginate aerogel	Methacrylic acid-ethyl acrylate	13% of the drug was released from coated aerogels in 30 minutes, and hence achieved the slowest release rate (70).
Gliclazide microparticles	Eudragit® NM 30 D	Sustained gliclazide release was obtained upto 15 h, incorporating the particles into the jellies significantly lowered the DR rate (71).
Ibuprofen microcapsules	Methacrylate copolymer	Developed chewing taste-masking particles (72).
Berberine hydrochloride orally disintegrating tablet	Eudragit E100	Remained stable after 6 months (73).
Naproxen sodium granules	Eudragit® E	Masked the taste of naproxen sodium (74).
Microcapsules of diclofenac sodium	Hydroxypropyl cellulose, polyethylene glycol 6000, an undercoat of Eudragit L30D, and Eudragit RS30D.	SR of highly water-soluble DS was obtained (75).
Metformin hydrochloride microcapsules	EC 45cps, EC100cps, DBS	The normal particle distribution and notable prolonged DR were reflected (76)
Amorphous Celecoxib (CLB) solid dispersion layered particles	Microcrystalline cellulose, polyvinyl alcohol (PVA), inulin, and polyvinyl acetate phthalate	Quick dispersibility along with high DR (77).
Microcrystalline cellulose cores	Eudragit® NM 30 D and Eudragit® RS/RL 30 D	For oral sustained release of liquid medicine (9).
Diclofenac sodium pellets	Acryl-Eze® MP	The drug content as well as release profiles were significantly affected by storage at 40 °C and 75% relative humidity (78).

8. Scalability challenges of multiparticulate Wurster coating

The Wurster coating process, especially when applied to multiparticulate systems, can face scalability challenges that may impact the efficiency and consistency of the coating. Here are some scalability challenges associated with multiparticulate Wurster coating:

- **Inhomogeneous Coating Distribution**

As the scale of the coating process increases, achieving uniform coating distribution on each individual particle becomes more challenging. Coating thickness variation among particles may lead to inconsistent DR profiles in the final product.

- **Airflow Distribution**

Maintaining uniform airflow across a larger coating chamber can be challenging. Inhomogeneous airflow may result in uneven coating distribution on the particles. This issue is critical for multiparticulate systems, where each particle needs to be individually coated.

- **Process residence time**

Achieving the optimal residence time for each particle in the coating chamber becomes more complex at larger scales. Variations in residence time can affect the thickness of the coating and the

overall quality of the final product.

- **Scale-up of process parameters**

Scaling up from laboratory-scale to production-scale introduces challenges in adjusting process parameters. Factors such as air velocity, spray rate, batch size, mass effect, and bed height must be carefully optimized to maintain coating uniformity, and this optimization can be challenging at larger scales.

- **Equipment design and scale-up**

The design of Wurster coating equipment for large-scale production must account for factors like bed dynamics, particle movement, and spray pattern. Scaling up equipment without addressing these factors may result in suboptimal coating performance.

- **Heat and mass transfer challenges**

Larger-scale processes may face challenges related to heat and mass transfer. Ensuring consistent drying of coated particles becomes crucial, and variations in drying rates can affect the final product's quality.

- **Agglomeration issues**

Agglomeration of particles is a common concern during the coating process. At larger scales, the risk of particle agglomeration may increase, leading to non-uniform coatings and potential quality issues.

- **Powder handling challenges**

Handling and transferring larger quantities of coated particles pose logistical challenges. Issues such as powder flow, segregation, and static electricity can become more pronounced at larger scales.

- **Cleaning and validation**

The cleaning and validation processes become more complex as the scale increases. Ensuring proper cleaning and validation of large-scale equipment is crucial for maintaining product quality and compliance with regulatory standards.

- **Environmental considerations**

As the scale of production increases, the environmental impact of the coating process, including solvent usage and waste generation, becomes more significant. Addressing sustainability concerns can add complexity to the scale-up process.

Addressing these scalability challenges requires a systematic and careful approach to process optimization, equipment design, and quality control. Pilot studies and thorough validation processes are essential to ensure a successful scale-up of multiparticulate Wurster coating processes in pharmaceutical and other industries (79,80).

9. Strategies to overcome limitations in microparticulate drug delivery

Important variables and their impact on the result should be determined in the lab before attempting to scale up. It will be very simple to scale up and scale out the formulation if the scale up activity begins at the development stage. The Wurster process involves 'n' variables. Certain ones, like batch size, concentration, spray liquid viscosity, base plate, column height, and dew point, are simple to determine. To adjust dependent variables such as spray rate, product temperature, atomization air pressure, and air volume, conduct some trials. Small-scale variable understanding is simple and requires less money and effort. Lastly, use design of experiments (DoE) to alter the most important parameter as per regulatory requirements. One can use statistical software like DoE software to minimise the number of trials further. To further reduce the number of trials, statistical software such as DoE software can be utilized. Adjust the parameter ranges and validate the procedure based on the results of the statistical analysis to ensure reproducibility and freeze the parameter. Typically, a 6-inch Wurster is used for product development, with batches ranging from 0.5 to 2 kg. The Wurster spray nozzle and column are small. Overall coating zone is small. The 18" Wurster pilot model, which has a significantly larger Wurster column and base plate, is recommended. When the spray rate exceeds nozzle capacity, large droplets of coating fluid appear along with small droplets to maintain uniform atomization; large droplets lead to the

formation of agglomerates. Use multiple unit nozzles to prevent agglomeration (79,80).

CONCLUSION AND FUTURE DIRECTIONS:

The integration of MDDS with the Wurster coating technique represents a promising advancement in pharmaceutical technology, addressing critical challenges associated with oral sustained-release dosage forms. While traditional sustained-release tablets may pose difficulties for older individuals with swallowing issues or others, MDDS offers a solution by encapsulating drugs in inert polymeric shells of 1 to 1000 μm size. This not only ensures biocompatibility, stability, and target specificity but also enables controlled and sustained release, reducing toxicity and enhancing treatment efficacy. The Wurster coating technique is a cost-effective and industrially scalable method for preparing drug-loaded microparticles. Therefore, the comprehensive review emphasizes the significance of this intelligent approach of MDDS and the Wurster coating technique presents a novel and effective strategy in pharmaceutical processes. Overall, this strategy holds great potential for transforming the landscape of sustained-release drug delivery, making it more accessible and beneficial for a diverse patient population in the future.

CONFLICT OF INTEREST:

The authors declare no conflict of interest.

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