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Review Article

Concept And Recent Advancement In Tablet Coating Technologies: A Comprehensive Review

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ABSTRACT

Tablet coating, an enduring pharmaceutical process, involves the application of a dry outer layer to confer specific benefits on the dosage form, such as taste and odor masking, physical and chemical protection, protects the drug from the gastric surroundings, and control over release profiles. This technique, applicable to various solid oral forms, including particles, powders, granules, crystals, pellets, and tablets, employs a sugar or polymeric coat. Traditional methods, like sugar coating, film coating, and enteric coating, were once prevalent, but recent advancements have circumvented their limitations. Modern coating technologies directly apply materials onto tablet surfaces without solvents, aligning with ICH guidelines advocating the avoidance of organic solvents for pharmaceutical safety. This comprehensive review elucidates the fundamental tablet coating concepts, types of coating, advantages, objective, recent technological strides, challenges encountered in the process, their solutions, and methods for coating evaluation.

INTRODUCTION

A tablet is a solid pharmaceutical dosage form that includes a blend of active substances and excipients, often in powder form, compressed or compacted into a stable form. Tablets are widely preferred globally, as almost all drug molecules can be formulated in this dosage form due to its simplicity and flexibility in the manufacturing process. Coating is a method in which a dry, outer layer of coating material is applied to the surface of a dosage form to achieve specific benefits. This coating process is applicable to various oral solid dosage forms, including tablets, capsules, multiparticulates, and drug crystals. [1] During the coating process in a coating pan, a batch of capsules or tablets acquires a polymeric film that transforms from a sticky liquid to a tacky semisolid and eventually to a non-sticky dry surface. This coating is applied to many solid pharmaceutical dosage forms, either externally on

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the tablet surface or on substances contained within gelatin capsules. The purpose of the coating is to facilitate the gradual release of the medication, ensuring the drug is available for digestion. The coating procedure can be precisely formulated to control the rate of tablet dissolution and the absorption location of the active ingredients in the body after ingestion. [2] The practice of coating pharmaceutical dosage forms dates back to ancient times. Early practitioners like Rhazes utilized psyllium seeds mucilage to mask the taste of pills, while Avicenna coated pills with silver and gold. Various materials were employed for coating, including talc for pearl coating, introduced by White, and gelatin coating, introduced by Garot in 1838. In 1842, the first sugar-coated pill was imported to the United States from France, and by 1856, a pharmacist in Philadelphia began indigenous manufacturing of coated pills. Initially, coating was done for extemporaneous compounding, but it later became a standard practice in the pharmaceutical industry on a large scale. [3] The coating composition, applied in a coating pan to a batch of capsules, forms a protective polymeric film on the tablet surfaces. As the tablet coating progresses, transitioning from a sticky liquid to a tacky semisolid and eventually to a non-sticky dry surface, it plays a crucial role in pharmaceutical dosage forms. Coatings can be applied externally on tablets or to substances within gelatin capsules, ensuring controlled drug release and optimal absorption in the body during digestion. The entire coating process is efficiently carried out in a series of routinely operated acorn-shaped coating pans, ranging from smaller ones for experimental purposes to larger pans for industrial production. [4]

The fundamental principles of tablet coating involve-

- Applying a coating composition to a moving bed of tablets while utilizing heated air for solvent evaporation.
- The objectives of tablet coating can vary, encompassing minimal influence on the release pattern,
- Modified release tailored to specific requirements
- Color coating for insulation
- Incorporation of additional drugs to prevent chemical incompatibilities or enable sequential release,
- Enhancement of pharmaceutical elegance through the use of special colors and contrasting printing. [5]

Objectives of coating- The objectives of tablet coating are as follows:

- Conceal tablet odor, color, or taste.
- Preserve active ingredient integrity.
- Regulate drug release.
- Incorporate compatible drugs.
- Protect acid-labile drugs.
- Enhance dosage form strength. [6]

Primary components of tablet coating-

1. Tablet properties- Tablets intended for coating should possess certain properties to ensure effective and uniform coating. These properties include:

- Tablets must exhibit resistance to abrasion and chips
- making the ideal shape for coating a sphere
- The tablet hardness should be equal to or less than 5 kg/cm2, & good friability is desired
- To withstand the heavy attrition of tablets striking each other or coating equipment walls
- tablets must be resistant to abrasion and chipping
- Tablets with a brittle and soft surface in the presence of heat are deemed unacceptable for film coating. [7]

2. Coating process- Achieving uniform and crack-resistant tablet coatings is essential. Various techniques have been developed for coating tablet surfaces, with common methods involving spraying coating solutions onto agitated tablets in a pan or fluid bed. As the solution is applied, a thin film adheres to each tablet. Evaporation of the liquid portion occurs by passing air over the tumbling pans, forming the coating. This process may involve a single application or the development of layers through multiple spraying cycles, with rotating coating pans frequently employed in the pharmaceutical industry. [8]

3. Coating equipment- Several types of equipment are used in tablet coating processes, each designed to achieve specific coating objectives. Some common coating equipment includes:

- Standard Coating Pan
- Perforated Coating Pan
- Fluidized Bed Coater / Air Suspension System

Standard Coating Pan- The standard coating pan is a circular steel pan, ranging from 8 to 60 inches in diameter, set on an angled stand and rotated by a motor. Hot air is directed onto the pan and tablet bed surface, with exhaust ducts positioned in the front. Coating solutions are applied to the rotating tablet bed through spraying or ladling, and an atomizing system ensures even distribution, reducing drying time in processes like sugar-coating or film coating. [9]

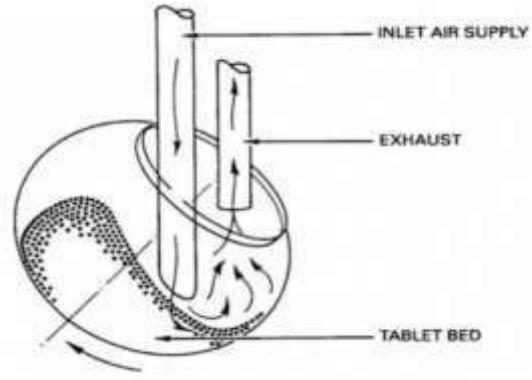


Fig 1. Standard Coating Pan [10]

Perforated Coating Pan- These systems utilize either totally or partially perforated drums that rotate in an enclosed housing on a horizontal axis. This method enhances coating material drying compared to conventional approaches, representing a significant time-saving. A crucial element in Glatt's design is the integrated Wash-in-Place/Clean-in-Place (WIP/CIP) system, ensuring thorough cleaning of the coating drum and interior housing. This system, combined with a watertight housing, allows for efficient maintenance. Hinged access doors on both sides of the housing facilitate easy cleaning, inspection, and maintenance of exhaust and inlet air connections. Glatt's Ramsey, New Jersey facility offers pilot scale equipment for testing and development purposes. [11]

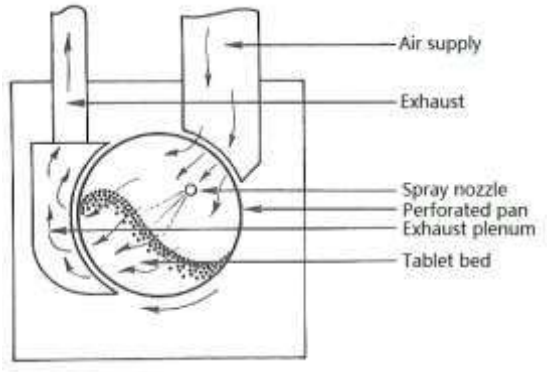


Fig 2. Standard Coating Pan [12]

Fluidized Bed Coater / Air Suspension System- Fluidized bed coaters use an air suspension system for highly efficient drying. Tablets are fluidized in a columnar chamber by upward-flowing drying air, controlled to draw more air into the center, causing tablets to rise. Coating solutions are continuously applied at the chamber's bottom through a spray nozzle positioned above the bed. This system offers precise control over the tablet movement inside the main column. [13]

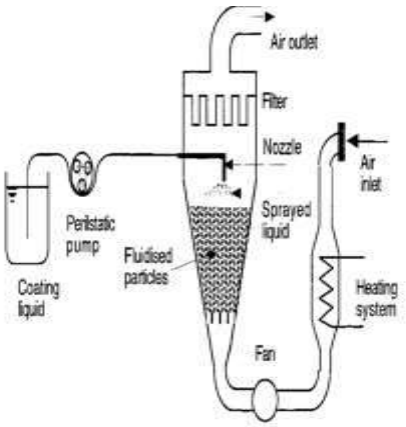


Fig 3. Standard Coating Pan [14]

Different method of tablet coating-

The tablet coating process enhances the effectiveness and ease of ingestion of pharmaceutical drugs in solid dosage form. Although tablet coatings share common functions like masking taste and odor, as well as ensuring shelf-life protection, various types of coating materials exist, each coating the surfaces differently and influencing the final outcome of the medication uniquely. [15]

Types of coating materials for tablets- Tablet coating involves applying a coating material to the tablet's surface to achieve desired properties, distinguishing it from the uncoated variety in the dosage form. Tablet coating encompasses three primary processes: sugar coating, film coating, and enteric coating. The choice of pharmaceutical coating materials is diverse and depends on the coating phase. These materials can be classified into

- binders (such as acacia, gelatin, and cellulose derivatives)
- fillers (like calcium carbonate, titanium dioxide, and talc)
- colorants (including dyes, iron oxides, and titanium dioxide)
- antiadhesives (such as talc). [16]

TRADITIONAL COATING TECHNIQUES-

Generally, three traditional methods are used for tablet coating they are as follows-

1. SUGAR COATING- The sugar-coating process for tablets entails layering coating materials on tablet cores by repeatedly applying a coating solution or suspension and then drying off the solvent. This method serves to insulate and conceal the color and texture of the tablet core. Sugarcoating of tablets has become less prevalent in the pharmaceutical industry as it has been supplanted by polymer film coating. Typically water-soluble, sugar coating facilitates rapid dissolution upon contact with liquids, such as gastrointestinal fluids. This coating serves to safeguard the drug within the tablet, acting as a barrier against external contaminants. Additionally, it can conceal the unfavorable taste of the drug, making it more palatable for some patients. The sugarcoating process also provides insulation and conceals the color and texture of the tablet's core. [17]

Materials used in sugar coating-

1. Sugar & its Substituents: Glucose, Lactose, Isomalt, Sugar Alcohols: These serve as the primary sweetening agents and can include glucose, lactose, isomalt, and various sugar alcohols.

2. Binders: Acacia, Gelatin, PVP (Polyvinylpyrrolidone): Binders such as acacia, gelatin, and PVP are used to facilitate the adhesion of sugar coating to the tablet cores.

3. Colouring Agents: Water-soluble (Dyes), Water-insoluble (Lakes): Dyes and lakes are employed as colouring agents to provide an appealing and distinct appearance to the coated tablets.

4. Anti-Adherents: Talcum, Colloidal Silica: Anti-adherents like talcum and colloidal silica prevent sticking and ensure a smooth coating process.

5. Fillers: $CaCO_3$, $CaSO_4$, Starch, Talcum, TiO_2: These materials act as fillers, enhancing the tablet's structure and aiding in the overall coating process. Common fillers include calcium carbonate

(CaCO3), calcium sulfate (CaSO4), starch, talcum, and titanium dioxide (TiO2).

6. Polishing Agents: Beeswax, Carnauba Wax, Paraffin: To achieve a desired luster and finish, polishing agents like beeswax, carnauba wax, and paraffin are applied during the sugar-coating process.

7. Other Agents: Flavoring Agents, Surfactants: Additional ingredients such as flavoring agents and surfactants may be included to enhance taste and aid in the uniform application of the coating. (18)

Process of tablet sugar coating-

The sugar-coating process for tablets involves several meticulous steps to achieve the desired appearance, protection, and identification. Each step contributes to the overall quality of the sugar-coated tablet. Here is an overview of the key steps:

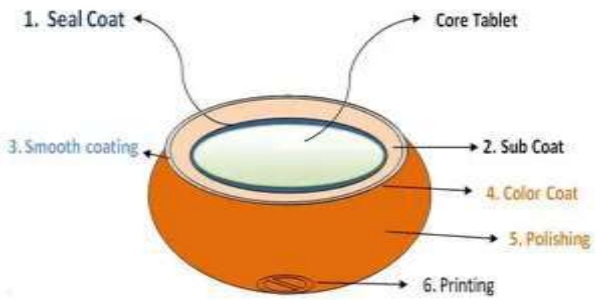


Fig 4. Steps involved in sugar Coating of Tablets (19)

1. **Sealing:** This step provides a moisture barrier to the tablet and hardens its surface.
2. **Sub coating:** Sub coating is performed to round the edges of the tablet and increase its weight.
3. **Grossing/Smoothing:** This step fills up imperfections from the sub coating stage and further increases the tablet size to predetermined dimensions.
4. **Coloring:** The final color is applied to the tablet during this stage of the process.
5. **Polishing**: This operation is carried out to achieve the desired luster on the surface of the tablet.
6. **Printing:** In the final stages of sugar coating, additional steps such as printing are undertaken to enhance the identification and branding of tablets. This process involves the application of pharmaceutical-branded ink either after or before the polishing phase. (20)

2. FILM COATING- Numerous coating techniques have been developed, both solvent-based and solvent-free, to enhance the efficiency of the coating process. However, each method comes with its own set of advantages and disadvantages, often requiring continuous technical refinement. The technology-driven process of tablet film coating relies on advancements in coating technology, equipment, analytical techniques, and coating materials for its evolution. Achieving intra- and inter-batch coating uniformity is crucial in film coating processes to ensure the quality of the final product, particularly in active film coating scenarios where the active pharmaceutical ingredient is part of the coating layer. Ongoing efforts involve the exploration of modeling approaches to predict the impact of operational parameters on final product quality and optimize process variables in tablet film coating. (21)

Materials used in film coatings-

1. Polymers- The film's main component is the polymer, responsible for forming the film. An ideal polymer should create consistent, thin films under regular coating conditions. The materials for film formers can be natural, synthetic, or semi-synthetic, offering a broad range of options. These include cellulose ether derivatives like hypromellose, methylcellulose, hydroxypropylcellulose, and sodium carboxymethylcellulose. Additionally, there are vinyl polymers such as polyvinyl alcohol and polyvinylpyrrolidone, as well as

polymethacrylates, mainly copolymers of butylmethacrylate, methacrylate, & methylmethacrylate. Other polymers like zein, modified starches, & polysaccharides.

2. Plasticizers- They alter the inherent properties of the polymer, making it more manageable for processing and enabling it to function as membranes. Only a select few plasticizers are approved for pharmaceutical use, including polyols like glycerol and propylene glycol, organic esters such as phthalates, dibutyl sebacate, triacetin, and vegetable oils like castor oil. Plasticizers, such as glycerol, propylene glycol, polyethylene glycols, and others, are incorporated into coatings to aid in processing.

3. Miscellaneous additives- Additives play diverse roles in coatings; colorants, like amaranth or γ-carotene, are employed for product individualization through color, using pigments or dyes such as aluminum lakes. Opacifiers, such as talc and titanium dioxide, are utilized to impart opacity. Fillers and anti-tack agents, including talc, microcrystalline cellulose, glyceryl monostearate, stearic acid, and magnesium stearate, are added to provide coating solids to the formulation and reduce tackiness.

4. Solvents- Solvents play a crucial role in achieving uniform film formation across the substrate. Examples such as water, ethanol, ethanol/water, and various solvent/solvent mixtures have been utilized for film coating based on empirical considerations, qualitative assessment of intermolecular forces, and quantitative evaluation using solubility parameters. While organic solvents were predominant until the early 1970s, concerns about cost, toxicity, and environmental impact led to a shift towards aqueous-based systems, making water the preferred coating medium today, though some companies still opt for organic solvents. [22]

Types of film coating- There are three main types of film coating for tablets:

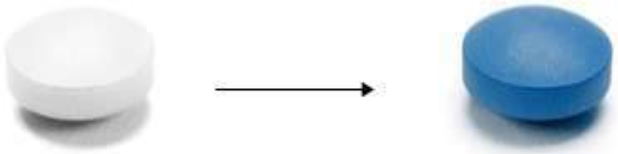
1. **Organic solvent-based coating:** This method involves using organic solvents to apply protective coatings to oral dosage forms, extending the shelf life of the drug. However, it can be risky due to potential toxicity and flammability.
2. **Aqueous coating:** This is the most common film coating method, using water instead of organic solvents. It is a safer option, avoiding the toxic and flammable nature of solvents. Aqueous film coating requires water-insoluble polymer mixtures & a plasticizer.
3. **Solvent-free coating:** Ideal for heat-sensitive drugs, this method doesn't require a drying phase. The result is an inert film coating that doesn't react with the active ingredients. Techniques include injection molding coating, hot-melt coating, and spray congealing. [23]

Process of tablet film coating-

The film-coating process entails the application of a coating solution onto a tablet bed in a pan coater, followed by immediate drying to create a thin, uniform film on the tablet surface. Three main coating methods are commonly used: modified conventional coating pans, fluid bed equipment, and side-vented pans. The process parameters influencing film formation and coating uniformity include the method of atomization of the coating suspension, the tablet bed movement ensuring adequate mixing, and the provision of sufficient heat input for rapid drying. Tablet properties (size, shape, porosity, hardness, density, pan loading) and equipment-specific parameters (pan diameter, geometry, baffle configuration) also play crucial roles in determining coating quality. [16]

Fig 5. Process of tablet film coating [24]

3. ENTERIC COATING- Enteric-coated tablets are specifically designed pharmaceutical tablets featuring a protective layer known as an enteric coating. This coating, composed of polymers, serves a crucial purpose – preventing the tablets from dissolving in the acidic environment of the stomach. This protective measure is essential for certain drugs, ensuring they remain intact until reaching the less acidic environment of the small intestine where absorption occurs. [25]



Materials utilized in enteric coatings-

Various materials are employed in the formulation of film coatings for pharmaceuticals to achieve specific properties. These materials include:

- Methyl Acrylate-Methacrylic Acid Copolymers
- Cellulose Acetate Phthalate (CAP)
- Cellulose Acetate Succinate
- Hydroxypropyl Methyl Cellulose Phthalate
- Hydroxypropyl Methyl Cellulose Acetate Succinate (Hypromellose Acetate Succinate)
- Polyvinyl Acetate Phthalate (PVAP)
- Methyl Methacrylate-Methacrylic Acid Copolymers
- Shellac
- Cellulose Acetate Trimellitate
- Sodium Alginate
- Zein
- Enteric Coating Aqueous Solution (Ethylcellulose, Medium Chain Triglycerides [Coconut], Oleic Acid, Sodium Alginate, Stearic Acid) (Coated Softgels) [26]

Process of enteric coating of tablet-

The process of enteric coating tablets involves applying a protective coating to the tablet cores to prevent them from dissolving in the acidic environment of the stomach. This coating is usually made of enteric polymers that resist dissolution in acidic pH but dissolve in the more neutral pH of the small intestine. [27]

The process typically includes the following steps:

Step i-undercoat- The undercoat plays a crucial role in reinforcing the tablet cores and setting the foundation for the subsequent enteric coating process. In this particular case, about 2% of film coating solids are applied to aspirin tablet cores, utilizing a film coating solution with a concentration of 12.5% solids. The application of this undercoat involves specific processing steps to achieve the desired outcome.

Step ii-enteric coat- In the second step of the process, approximately 7.25% of enteric coating solids are applied to the tablet cores from Step I. This is accomplished by utilizing an enteric coating solution with a concentration of 15.5345% solids. The application of this enteric coating is a crucial phase in the overall tablet coating procedure.

Step iii-overcoat- About 3% film coating solids are administered to the tablet surface utilizing the identical film coating solution as outlined in Step I and implemented in a comparable fashion.

Step iv-polishing- In the final stage, the color-coated tablets from Step III undergo a polishing process in the coating pan with the exhaust turned off. This involves sprinkling 0.01% powdered polishing wax onto the tablet bed while rotating slowly. The tablets are rolled in the pan until they

begin to slide. Subsequently, the exhaust is turned on to eliminate excess wax. As a result, the finished enteric film-coated tablets have approximately 12.5% total film coating solids applied, enhancing their overall appearance and quality. [28]

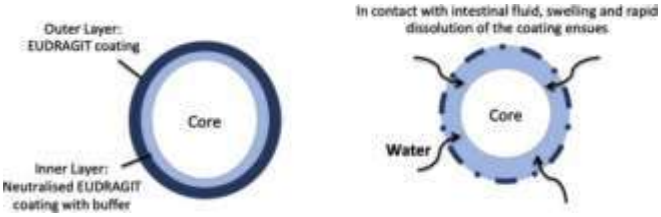


Fig 6. Process of enteric coating tablet [29]

Tablet coating defects and remedies-

Identifying and addressing tablet coating defects is a crucial aspect for pharmaceutical formulation scientists, marking the final critical step in the tablet production cycle. Once challenges in the core tablet manufacturing have been resolved, focusing on tablet coating defects and their remedies becomes essential to ensure the successful completion of the entire tablet production cycle. [30]

Table No. 1 tablet coating defects and remedies. [31,32,33]

Defects	Definition	Causes	Remedies
Blistering	Blistering occurs when the film detaches from the tablet surface, forming blisters.	This defect, blistering, may occur due to the entrapment of gases in the film layer during the spraying process, particularly when the process is overheated.	To address the blistering defect, one can consider implementing mild drying conditions during the tablet coating process.
Chipping	Chipping occurs when the film on the tablet surface becomes dented or chipped from the edges.	The occurrence of chipping on the tablet surface may be attributed to a reduced rotation of the drum or inadequate flow of fluidizing air in the coating pan.	It is crucial for the operator to exercise caution during the pre-heating stage and avoid over-drying the tablets to prevent them from becoming brittle, which could contribute to the occurrence of chipping.
Picking	Sticking, in tablet coating, refers to the situation where the film adheres to the tablet's surface and may be torn away, leading to tablets sticking together.	To prevent the sticking defect, it's essential to ensure thorough drying of the tablets during the coating process and avoid the production of wet tablets.	To address the sticking defect, one can consider reducing the volume of the applied liquid or increasing the temperature of the dry air during the coating process.
Pitting	It is characterized by specific pits on the surface without the disappearance of the film coating, may be addressed by adjusting the coating process parameters.	The issue of pits on the tablet surface may arise from the materials used having a melting point lower than the temperature of the tablet core in the formulation.	Fine-tuning the temperature during the tablet core process can eliminate the occurrence of such defects.
Roughness/Orange peel	This surface defect, resembling an orange and lacking gloss, is attributed to the film's appearance.	The lack of proper dispersion of the coating solution before drying can lead to this issue.	Adding an extra solvent to thin the solution can correct this problem.

Color variation	Color variation, as a defect, leads to discrepancies in the color of the film on the tablets.	The occurrence of color variation defects can be attributed to factors such as inconsistent duration of tablet exposure in the spray zone & variations in the frequency, shape, and size of the spray zone.	To address the instability caused by the ingredients, reformulating with different additives and plasticizers is the most effective solution.

CONCLUSION

Coating solid dosage forms serves various purposes, with paramount importance placed on controlling the release profile and influencing the bioavailability parameters of Active Pharmaceutical Ingredients (APIs). Tablets containing these APIs can undergo coating with a thin polymer-based film, offering a range of advantages in pharmaceutical formulations. Over the past three decades, considerable developmental endeavors have been directed towards the coating of pharmaceutical formulations, notably in tablet coating, with a primary focus on ensuring and augmenting final product quality. Notable advancements in areas such as energy efficiency, film distribution, drying processes, and the adoption of continuous processing have substantially propelled the evolution of this technology, concurrently improving safety profiles. Looking ahead, the future holds vast potential for further developments in tablet coating, offering opportunities to achieve specific and targeted benefits.

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