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REVIEW ARTICLE

Comprehensive Review on Tablet Coating Problems and Remedies

Mounika Dumpa*[1] , Madhavi Kamadi[1], Anilkumar Vadaga[2]

[1] *Student, Department of Pharmacy Practice, GIET School of Pharmacy, Rajahmundry, Andhra Pradesh, India*
[2] *Associate Professor, GIET School of Pharmacy, Rajahmundry, Andhra Pradesh, India*

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Abstract: Pharmaceutical coating plays a crucial role in enhancing the organoleptic properties of solid pharmaceutical dosage forms. The tablet coating process is particularly pivotal for manufacturing tablets with controlled or delayed release profiles, improving the stability of dosage forms. This coating can be applied to various oral solid dosage forms like particles, powders, granules, crystals, pellets, and tablets. However, troubleshooting problems such as twinning, mottling, and chipping may occur due to faults in tablet core, coating formulation, or coating process. Overcoming these issues is essential to prevent unnecessary product complications. When a coating composition is applied, a tacky polymeric film covers the tablet surfaces. Various techniques, including sugar coating, film coating, and enteric coating, have been employed, with recent advancements minimizing the drawbacks associated with older methods. Modern coating technologies directly apply coating materials to the tablet surface without using solvents, aligning with ICH guidelines that emphasize solvent-free formulations for pharmaceutical safety. This review discusses the fundamental aspects of tablet coating, outlines common process challenges, and explores potential remedies.

Keywords: Tablet coating; Mottling; Polishing; Evaluation; Chipping; ICH guidelines.

1. Introduction

Oral drug delivery is a non-invasive and highly convenient administration method [1,2]. Tablets offer precise dosing, chemical and microbiological stability, controlled release characteristics, ease of use, cost-effectiveness, and an aesthetically pleasing form, making them the most widely utilized dosage form [3]. As per the IP, pharmaceutical tablets are solid, flat, or biconvex unit dosage forms prepared by compressing drugs with or without diluents [4].

Key tablet properties include [5-7]:

- Elegance and identity without defects like chips, cracks, discoloration, or contamination.
- Sufficient strength to endure shocks during production, packaging, shipping, and dispensing.
- Physical stability to maintain characteristics over time.
- Predictable and reproducible release of the medicament agent in the body.
- Appropriate chemical stability to prevent alteration of medicinal agents over time. [1-4]

Tablet Coating involves applying an outer layer to a dosage form for specific benefits, such as controlling dissolution rate and drug absorption. Modern coating systems include a pan, spraying equipment, air handling device, and dust collector [8,9]. Purpose of tablet coating include:

- Provide physical and/or chemical protection to the drug, shielding it from environmental factors for improved stability.
- Mask unpleasant odor, color, and taste.
- Enhance patient compliance.
- Protect the drug for stability.
- Enhance overall drug protection.
- Safeguard acid-labile drugs in an acidic medium.
- Alter drug release patterns.
- Increase packaging speed and reduce friction between tablets.
- Improve mechanical strength of tablets.

* Corresponding author: Mounika Dumpa

The advantages of tablet coating are: Increase shelf life, facilitate easier swallowing of large doses, prevent loss of volatile substances, combine incompatible medications into a single dose, enhance product durability and mask batch differences in raw material appearance. On the other hand, the disadvantages of this process are: interference with pharmacodynamic characteristics, complex procedure, increase in formulation costs and may result in film defects like mottling, capping, chipping, bridging, etc [10-14]. The main aim of this review is to explore the fundamental aspects of tablet coating, outlines common process challenges, and explores potential remedies

2. Types of tablet coating

2.1. Sugar coating

Sugar coating involves multiple steps to achieve the desired characteristics of tablets. The process begins with sealing, where a moisture-resistant coat is applied to prevent water penetration into the tablet core. Subcoating follows, involving the addition of multiple sugar-based layers to increase tablet weight and provide rounding. Smoothing is the subsequent step, requiring additional coatings of a thick syrup to complete rounding and smooth the coating. The finishing and coloring stage involves applying several coats of a thin syrup containing desired colorants for final smoothness and color. Finally, polishing is done by applying powdered wax, such as beeswax or carnauba, to achieve the desired luster. Throughout these steps, various techniques like warm air application and dusting powders are utilized to ensure proper tablet drying and shaping. [15-18]

2.2. Film coating

Film coating involves the application of a thin layer of polymeric material to tablets, capsules, or pellets, addressing various challenges encountered in drug product manufacturing, transportation, storage, and clinical use. It is a widely employed and adaptable technique in the pharmaceutical and food sectors. Film coating can be classified into non-functional and functional types. Non-functional film coating alters tablet appearance and protects from environmental factors, while functional film coating modifies or delays drug release, improving stability. Film coating methods include organic solvent-based, aqueous, and solvent-free coating. Organic solvent-based coating, although not ideal, is used for hydrophobic or lipophilic polymers. Aqueous film coating is widely used, offering advantages in safety and environmental aspects. Solvent-free coating, an alternative to alleviate disadvantages of solvent-based methods, saves time and money. Reasons for film coating include changing color, ensuring stability, and improving taste/odor. The equipment and process parameters for film coating are similar to those for sugar coating, involving methods like pan pour and pan spray. The pan pour method involves manual application and relies on the operator's skill, while the pan spray method employs an automated spraying system with various nozzle systems. [19-21]

3. Recent trends in tablet coating

Recent advancements in tablet coating technologies [22-24] include:

3.1. Electrostatic coating

- Conductive substances are effectively coated using this method.
- The substrate undergoes a significant electrostatic charge.
- The charged substrate is sprayed with a coating substance containing conductive ionic species with opposite charges, resulting in a comprehensive and homogeneous coating.
- Two types of spraying units are used: Corona charging and Tribo charging

3.2. Vacuum Film coating

- A revolutionary process utilizing a specially designed battled pan.
- The pan, which is hot and water-resistant, can be sealed to create a vacuum.
- Tablets are placed in the pan, and nitrogen displaces the air until the desired vacuum level is achieved.
- Coating solution is applied using an airless spray technique.
- A vacuum system extracts the vapors of evaporated liquids.
- Organic solvents can be effectively employed, making it environmentally friendly.

3.3. Compression coating

- A relatively uncommon technique with specific advantages.
- Useful when the tablet core cannot tolerate organic solvents or water, but coating is necessary for taste masking or enteric qualities.

- Simplifies the segregation of incompatible substances.
- Requires a specialized tablet machine.

3.4. Dip coating

- Involves dipping moist tablets into a coating liquid and drying them in traditional coating pans.
- Multiple alternating dipping and drying stages may be performed to achieve the desired coating.
- Spray coating processes are faster, more versatile, and more reliable compared to dip coating.

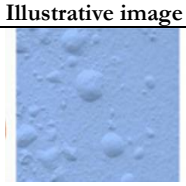
4. Evaluation of tablet coating

- The force required to peel the film off the tablet surface was measured using adhesion tests with tensile strength testers.
- A tablet hardness tester can be used to assess the diametral crushing strength of coated tablets.
- The rate of disintegration and dissolution of coated tablets must be determined.
- Stability studies in coated tablets are required to assess whether temperature and humidity fluctuations would induce film flaws.
- Measurement of tablet weight gain and exposure to elevated humidity provide information on the film's protection.
- Instrumental methods have been used in several studies to uniformly assess film surface roughness, hardness, and color. If no color transfers from a rubbing tablet to a white paper sheet, the tablet is abrasion-resistant. [25]

5. Tablet coating defects-their causes and remedies

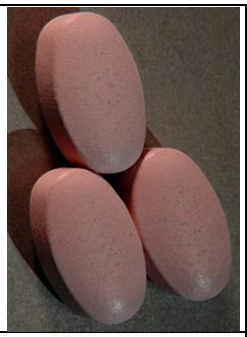
Various defects in tablet coating, their causes and remedial actions to be carried out to prevent such defects [26] are listed out in Table 1.

Table 1. Tablet coating defects-their causes and corrective actions

S.N	Tablet coating defect	Illustrative image	Causes	Corrective actions
01	**BLISTERING:** It's a coating defect in which the film separates from the substrate and forms a blister		Gas or vapor entrapment in or beneath the film as a result of overheating during the coating process or at the end. The effect of temperature on the film's adhesion, elasticity, and strength.	Use mild drying methods Use mild drying methods
02	**BLOOMING/DULL FILM:** It's a coating defect in which the coating turns dull when exposed to high temperatures for an extended period		Plasticizer concentration is high coating material with low molecular weight plasticizer	Lower the plasticizer concentration. Use a plasticizer with a high molecular weight
03	**BLUSHING:** It's a defect in the coating that causes whitish spots or haziness in the film		Coating polymer precipitation caused by a weak solvent or a high coating temperature The inclusion of sorbitol in coating formulations causes a significant drop in the thermal gelation temperature of HPMC, HPC, Cellulose ethers, and methylcellulose.	Reduce the temperature of drying air The use of sorbitol should be avoided with HPMC, HPC, Cellulose ethers, or ethylcellulose.
04	**CRATERING:** It's a film coating problem that causes volcanic-like craters on the tablet surface		Coating solution penetration at the tablet's surface, particularly at the crown where the surface is more porous, results in localized core disintegration. Ineffective drying Increased coating solution application rate. The viscosity of the coating solution is low	Reduce the spray rate and employ the optimum drying conditions possible. Use the optimum drying conditions possible Reduce the spray rate application increase the viscosity of the coating solution.

05	**CRACKING/SPLITTING:** It's a coating defect in which the film either cracks across the tablet's crown (cracking) or splits across the tablet's edges (splitting).		Polymeric blends of polymers with a high molecular weight The thermal expansion characteristics of the coating and the core are different Overheating causes core expansion The coating has a lower mechanical strength An insufficient coating formulation Inadequate plasticization or excessive pigmentation	Use polymeric blends of polymers of low molecular weight Mineral excipients should be avoided Do not overheat the tablet's core Use a coating that has adequate mechanical strength Use the right coating formulation
06	**COLOR VARIATION:** It's a color fluctuation in the film caused by the coating defect		Inadequate tablet mixing Suspension opacity is poor Inadequate drying coting or migration of soluble dyes, plasticizers, and other additives Inadequate spray gun setup Pan load(low/high) Core friability is high Insufficient spray guns A solid coating suspension with a high coating thickness The coating suspension has a low hiding power Coating suspension dispersion is uneven The coating suspension applied was insufficient	Mix geometrically Increase the suspension opacity Use a variety of plasticizers and additives in formulation, or use the optimum drying conditions possible Setup the piston correctly Load the appropriate quantity of tablets Reduce the core's friability Increase the availability of spray guns
07	**CHIPPING/EDGE EROSIONS:** It's a coating defect in which the film chips, wears away, and dents when the coating is applied, usually at the tablet's edges		Inadequate number of core tablets in the pan the baffles are designed incorrectly the coating film's strength is inadequate The pan speed is excessively fast Tablet punching/tooling damage Tablets have sharp edges The spray rate is low Suspension solid with low coating thickness The coating process causes a high level of attrition	enough core tablets should be placed in the pan make use of appropriate baffle design Make use of a high film strength coating formula Choose the right pan speed Tooling for tablets should be replaced Use the correct tablet shape
08	**CORE EROSION/SURFACE EROSION:** It's a coating defect that occurs when tablets fall during the coating process, causing the surfaces to deteriorate		The tablet core is hygroscopic The spray rate is too high or too low Pan speed is too fast The core tablet's friability is high Inadequate film strength to protect against edge damage Ineffective punch design Punch wear Ineffective logo design or location The solid low coating suspension	Reduce the number of hygroscopic excipients like disintegrants in the formulation Use the proper spray rate Use the proper pan speed Make the tablet less brittle Make use of strong film
09	**DISCOLORATION:** It's a rare coating defect in which discoloration appears through or on the coating due to interactions between components in the core or heat from the process causing core ingredients to migrate through the coating.		The solids in sprayable coatings are too low The film provides less moisture protection during storage Low temperature and rapid spray rate Reduced pan speed In the core, components migrate and melt	use a higher solids film coating formula Use a coating solution that provides enough moisture protection Reduce the spray rate or raise the processing temperature

10	**LOGO BRIDGING:** It's a coating defect that occurs when coating bridges from across a logo or break line		A coating system has poor plasticization Coating system with little adherence Ingredients with low adherence The spray rate is excessive Low product temperature Ineffective logo design.	Plasticizer coating should be used optimally Coating with a high adherence coating Use core ingredients with high adherence Lower the spray rate
11	**LOGO IN-FILLING/BREAK LINE IN-FILLING:** It's a coating defect in which the imprinted logo or break line is filled with hardened foam or dried polymer particles		High air pressure for atomization High air temperature for drying A solid coating suspension with a high coating thickness The gun to bed distance is too high The spray gun is poorly designed Turbulent airflow Coating suspension aeration Ineffective logo design The coating solution is excessively foamy Air spraying of a polymer solution causes foam and bubble production Excessive spray drying	Reduce the pressure of atomizing air Reduce the air temperature for drying Use a coating suspension with a low viscosity Reduce the gun to bed distance Use the appropriate spray gun design Reduce pan deflation To avoid aeration, use optimal suspension preparation
12	**ROUGHNESS/ORANGE PEEL**: It's a coating defect in which the applied film coating's surface is highly rough and non-glossy, giving it the appearance of orange skin		Quick-drying The viscosity of the coating suspension is too high The atomizing air pressure is too low Excessive wetting/high spray rate Ineffective spray gun performance Inadequate coating suspension distribution Gun to bed distance is extremely low	Use the gentle drying method Reduce the coating suspension's viscosity Increase the pressure of atomizing air Reduce the spray rate Upgrade the spray guns
13	**PITTING**: It's a coating defect in which pits emerge on the surface of a tablet core with no obvious film coating damage		Inappropriate drying temperature (inlet air) Lubricant melting or dissolution on the tablet surface, or core ingredient melting due to high core temperature	Use the proper drying temperature (inlet air) Use temperature control when drying
14	**PEELING:** It's a coating defect in which the tablet peels off during or after the coating procedure		Ingredients with low adherence The coating has a low mechanical strength Coating system with little adherence Due to high attrition effects, the coating is rubbing off	Use ingredients with high adherence Improve mechanical strength by using suitable composition Coat with a high adherence coating Reduce the pan speed
15	**STICKING AND PICKING:** It's a coating defect in which a portion of the tablet films stick together or sticks to the pan for a brief period after passing through the spray		Insufficient drying The coating solution has a high viscosity The spray rate is excessive Insufficient drying air volume The drying air temperature is too low The pan speed is too slow The atomization pressure is low Inadequate spray gun setup Solubility at the surface Tablet surface porosity is high	Use optimum drying conditions possible Coating solution viscosity is increasing Lower the spray rate Boost the air volume Increase the temperature of the input air Speed up the pan speed

16	**SCUFFING OF FILM-COATED TABLETS:** It's a coating defect that causes grey to black markings to emerge on the surface of white (or light-colored) film-coated tablets		The denser the core formulation, the larger the tablet Caplet shaped tablets or elongated forms The coating procedure lasts a long time The pan speed is too slow The amount of core tablet in the pan is insufficient	High-density mineral excipients like dicalcium phosphate and calcium carbonate should be avoided Use the relevant tablet shape Reduce the time of coating Speed up the pan Fill the pan with enough core tablets
17	**TWINNING:** It's a coating defect that causes tablets to stick together, particularly when two tablets are stuck together		Flat surfaces commonly found at the edges of the capsule-shaped tablets The coating formulation is very sticky Inappropriate tablet form The pan speed is too slow Spray droplet size is very huge The spray rate is too high Inadequate drying	Modify the tablet's shape Make use of a less sticky coating composition Use the right tablet shape Speed up the pan Increase the pressure of atomizing air
18	**TABLET BREAKAGE:** It's a coating defect in which the tablets break apart while being loaded into the pan, tumbling in the pan, coating, or unloading the coating pan.		The core tablets are very soft Tablets are fragile The coating tablet form is poor Ineffective baffle design Pan speed is too fast Tablet loading and unloading from the coating pan Less binder is employed in the formulation	Change the core formula Modify the core compression parameters Use the relevant tablet shape Modify the baffle design Lower the pan speed Load and unload the tablets with care

6. Conclusion

Tablets, the oldest and most widely used dosage form, were initially crafted by hand before suitable production equipment was developed. Coatings served to mask unpleasant tastes, protect active ingredients, and safeguard the gastrointestinal tract. Various coating processes were employed, each with its own merits and drawbacks, enhancing product quality. Coating regulates drug bioavailability and is applied to a fully functional dose form. However, defects may arise during coating, potentially diminishing product acceptability and efficacy. This review explores coating types, defects, factors influencing procedures, and associated pros and cons. There's a significant potential for future advancements in tablet coating technology to yield specific benefits.

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Author's short biography

Mounika Dumpa

Mounika Dumpa currently studying 5th year Pharm.D. She is very interested development of new pharmaceutical formulations.

Madhavi Kamadi

Madhavi Kamadi currently studying 5th year Pharm.D. She has an enormous interest in the medical research.

Anil Kumar Vadaga

Mr. Anilkumar Vadaga is an esteemed Associate Professor within the department of Pharmaceutics at the GIET School of Pharmacy, Rajahmundry. His academic journey reflects a deep-rooted passion for Pharmaceutics, marked by his unwavering commitment to the field. With his M. Pharm background, he has already acquired a strong foundation in pharmaceutical knowledge and principles. He also worked in the field of novel drug delivery system. His dedication and knowledge continue to inspire and shape the future of Pharmaceutical Sciences.