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A Review on the Concent and Recent Advancement in Tablet Coating Technologies

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ABSTRACT

Tablet coating can be done in numerous ways. In order to produce superior formulation quality (such as color, texture, mouth feel, and flavor masking), as well as to preserve the pharmaceuticals in the dosage forms chemically and physically and modify the properties of drug release, coatings play a critical role in the formulation of pharmaceutical dosage forms. The majority of film coatings are applied as polymer solutions with an organic or aqueous base. These film coatings have drawbacks of their own. An alternative coating process is solventless coating. Many of the drawbacks of using solvents in pharmaceutical coating—such as solvent exposure, solvent disposal, and solvent residue in the product—can be addressed by solventless coating technologies. By doing away with the costly and time-consuming solvent disposal and treatment procedures, solventless processing lowers overall costs.Furthermore, it can drastically cut down on processing time by skipping the drying and/or evaporation steps. With the exception of hot-melt coating, these environmentally friendly procedures are often carried out without the use of heat, offering a different approach for coating medications that are sensitive to temperature. The different solventless coating techniques that can be used to coat pharmaceutical dosage forms are covered in this article. These techniques include magnetic assisted impaction coating, hotmelt coating, supercritical fluid spray coating, electrostatic coating, dry powder coating, and photocurable coating.

Keywords DFs, FC, GIT, API

I. INTRODUCTION

The dose forms (DFs) that are most readily available in pharmacies are thought to be oral solid dosage forms. They started producing them more than a hundred years ago. These DF come with a number of benefits, one of which being their high patient compliance rate and comparatively simple and convenient manufacturing process. [1] One type of medication dose form is a tablet. It is made up of an excipient and active ingredient mixture that has been compressed or pressed into a solid, typically in the form of powder. Throughout the world, one of the most used dose forms is tablets. The majority of medicine compounds may be prepared as tablets, and the technique of making them is fairly straightforward and adaptable.[2]

The most notable member of this class, tablets, have been enhanced over the past few decades by the introduction of methods like twofold compression, tablet coating, and osmotic systems, which allow for controlled and targeted release.[3] Wax, polyhydric alcohol, plasticizer, flavoring and coloring agent, sugar, fillers, gums, and resins are a few possible ingredients in the coating composition. In contemporary coating, polymers and polysaccharides, coupled with plasticizers and pigments, are the fundamental coaters. Since the coating needs to be strong and durable, a number of safety measures need to be taken.In order to extend the shelf life of tablets that are susceptible to oxidation or moisture and to improve their swallowability by smoothing out or masking an off-putting taste, film coating is advised. Recently, a lot of research has been done in the area of covering dosage forms with polymers or biopolymers.[4]

Classification of Film coating:

1. Non-Functional Film coating

FC affects the final look and organoleptic characteristics of the manufactured tablets, which are regarded as crucial components of the brand image, and works in tandem with tablet shape and size to improve patient compliance.[5] Furthermore, because the presence of a film coat on the DF can ease swallowing, FC is crucial in helping elderly patients with dysphagia. [6] Comparing a tablet with a coating to one without, of equivalent size and form, the US FDA has stated that the presence of a coating can help or improve tablet mobility.[7] Furthermore, a major obstacle in

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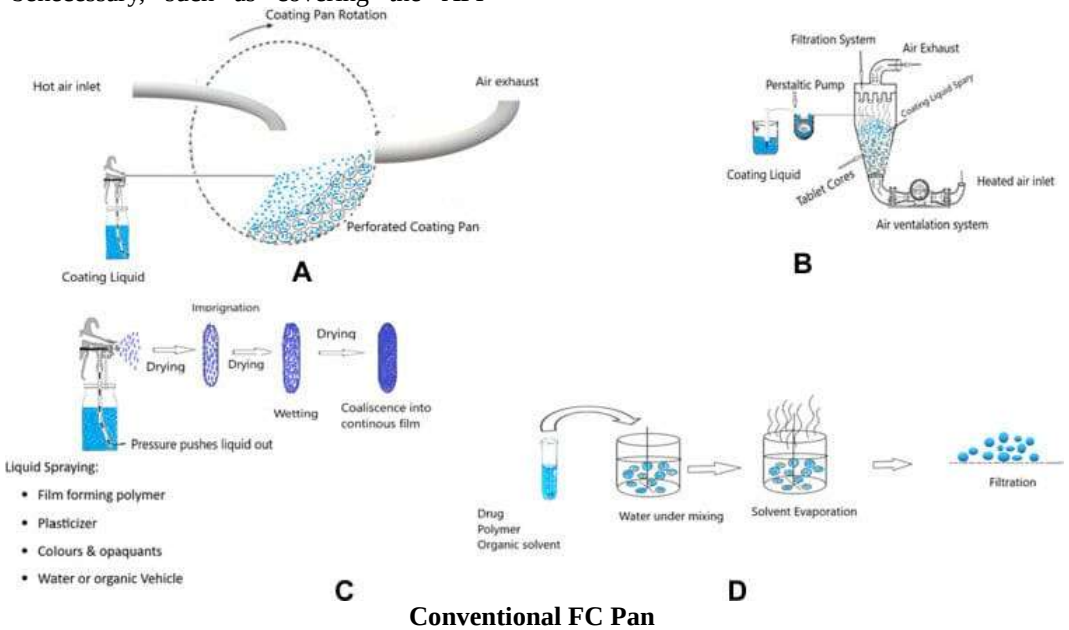
the development of oral liquid solutions is the unpleasant taste that many APIs have, especially for pediatric patients. Nonetheless, this discomfort can be remedied with a straightforward FC of the traditional oral slid DFs. The solubilized medication has less chance to interact with the taste buds since the polymer coat forms a physical barrier between them and the API. But for chewable pills, more advanced FC techniques might benecessary, such as covering the API crystals with a design intended to delay oral dissolving without changing the intended gastrointestinal tract (GIT) dissolution pattern in order to prevent any detrimental effects on drug bioavailability. As an illustration, the API can be coated with appropriate copolymers or polymers to create nano- or microcapsules, which can then be utilized to create chewable granules that conceal taste.



Conventional FC Pan

2. Functional Film Coating

Functional FC is mostly utilized to add new added value to the generated items, as we have stated previously in this review. One or more functions may be included in these values. Such as enhancing the product's stability and altering its release schedule to create products that target specific drugs. Table 1: Frequently Utilized Elements in Both Functional and Non-Functional FC

Function	Material Name
Functional FilmForming Polymer	Cellulose Acetate Phthalate Hydroxy Propyl Methyl Cellulose Phthalate Cellulose Acetate Trimellate Ethyl Cellulose Methacrylic Acid Copolymer Shellac
Non-Functional Film Forming Polymer	Hydroxy Propyl Methyl Cellulose Hydroxy Propyl Cellulose Polyvinyl Pyrrolidone Polyvinyl Alcohol High Molecular Weight Polyethylene Glyco
Solvent or Vehicle Plasticizers	water, Ethanol, Methylene Chloride Propylene Glycol, Polyethylene Glycols, Diethyl Phthalate, Fractionated Coconut Oil, Castor Oil
Colourants	Water-soluble Dyes (FD&C Yellow 5) Water-insoluble (FD & C Yellow 5 Lake) Inorganic Pigments (Iron Oxide Titanium Dioxide) Natural Colourants (Beta Carotene

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a) Product Stabilization

In the creation of pharmaceuticals, one of the most crucial objectives is thought to be product stability. As a result, careful work needs to be done to produce stable products that last the longest. This involves the use of specific moisture-resistant FC polymers, desiccants, and pack designs that are appropriate.

This measure is especially suitable for safeguarding the large product either before to packing or during transportation in the event that the packaging is carried out at a distant location. Additionally, it might make the substance more resilient to damp conditions once the bottle is opened, particularly if it will be repackaged in dose administration aids.[9]

b) Delayed-Release FC

Enteric-coated or delayed-release drug formulations (DFs) are frequently made with pH-sensitive polymeric coatings that can postpone the release of specific active pharmaceutical ingredients (APIs). This is done to shield the drug from the stomach's acidic environment (such as proton pump inhibitors) or to shield the stomach from the irritant effect of long-term use of non-steroidal anti-inflammatory drugs (APIs), such as diclofenac sodium.[10]

Enteric release polymers often have carboxylic moieties on their main chain, which renders them insoluble at pH values below 5 (Table 1). It has been usual practice to utilize these acid-resistant polymers to prevent medication release at pH 1.2. However, when the pH is greater than 5.5, they exhibit a notable increase in solubility, which allows the medication to pass through the stomach and enter the small intestine instead.[11]

C) Controlled Release FC

Extended-duration release Oral DFs were created to reduce the number of dosing schedules, particularly in cases where the medication needs to be taken for an extended length of time at a reasonably stable blood level. It has also been utilized for APIs that must be administered in large dosages but for which a quick release formulation runs the risk of unfavorable ulceration. This can be achieved by a variety of methods, including coating the API or the DF that contains the API, encasing the drug in an appropriate matrix, and creating complex forms between the API and ion-exchange resins.[12]

A multi-particulate (MP) delivery device distributes the API dose across the whole gastrointestinal tract. Because a few units failing will be far less dangerous than a single-unit tablet or capsule failing, which could result in dose dumping, this is a benefit over the single-unit coating. The nonpareil technique is accessible for MPs for this purpose. To obtain the desired release pattern, such as MR release profiles, enteric and/or targeted release, and/or pulsatile release, several functional and non-functional film seal coats are put over the nonpareil sugar particles coated with an FC that contains the AP. The many MP techniques, such as swelling/rupturing, dissolving and/or eroding, and altering the FC's intrinsic permeability, were summarized in a recent review.[13]

Objectives of Coating:

The objectives of tablet coating are as follows: To mask the disagreeable odor, color or taste of the tablet and increase patient compliance.
To offer a physical and/or chemical protection to the drug and protect drug from external environment (particularly air, moisture and light) in order to improve stability.

- To prolong the shelf life of the drug.
- To enhance ease of swallowing large dose forms.
- To retard loss of volatile ingredients
- To modify and/or control the rate of drug release as in repeat-action, delayed release (enteric coated) and sustain-release products.
- To incorporate incompatible drugs together in a single dosage form.
- Increasing the mechanical strength of the dosage form.
- Improving product appearance and help in identification by the manufacturer, the pharmacist and the patient (mostly colored).
- Masking batch differences in the appearance of raw materials.
- In improving product robustness.[14]

TABLET PROPERTIES:

The tablets that are going to be coated need to have the right physical attributes. When the coating material is applied, the tablets roll in a coating pan or tumble in the air stream of an air suspension coating.

The tablets need to be abrasion and chip resistant in order to withstand the severe attrition of hitting other tablets or the coating machine walls.

In the early stages of the coating process, tablet surfaces that are brittle, soften when exposed to heat, or that are impacted by the coating

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composition tend to become rough and are unsuitable for film coating.

A spherical tablet is the best shape for coating since it rolls easily in a coating pan and makes the least amount of contact between tablets. The less problems with tablet agglomeration there will be on a more convex surface.

The chemical makeup of the components used in the formulation determines the tablet's surface characteristics.

Advantages of Tablet Coating:

The drug's flavor, odor, or color are concealed by the coating of ablets.

Tablets coating control the release of the drug from the tablet.

It provides physical and chemical protection and protects the drug from the gastric environment of the stomach (acid resistant enteric coating(15)

Disadvantage of Tablet Coating:

Tablet coating increase the cost of formulation.

Tablet coating may interfere in Something coating may result in various film defects like, mottling, capping, chipping, bridging. The process remained complicated.[16]

COATING PROCESS:

Three types of equipments

A. Conventional Pan System

a. Pellegrini system
b. Immersion-sword system
c. Immersion –tube system

B. Perforated Pans Systems

a. Accela-coata
b. Hi-coater systems
c. Driacoater
d. Glatt coater

C. Fluid Bed Systems

A. Conventional pan systems:

A circular metal pan positioned on a stand at an angle is the basic component of the coating pan system. A motor rotates the 8–60 inch diameter pan on its horizontal axis. Ducts placed through the front of the pan are used to vent heated air that is directed into the pan and onto the tablet bed surface.

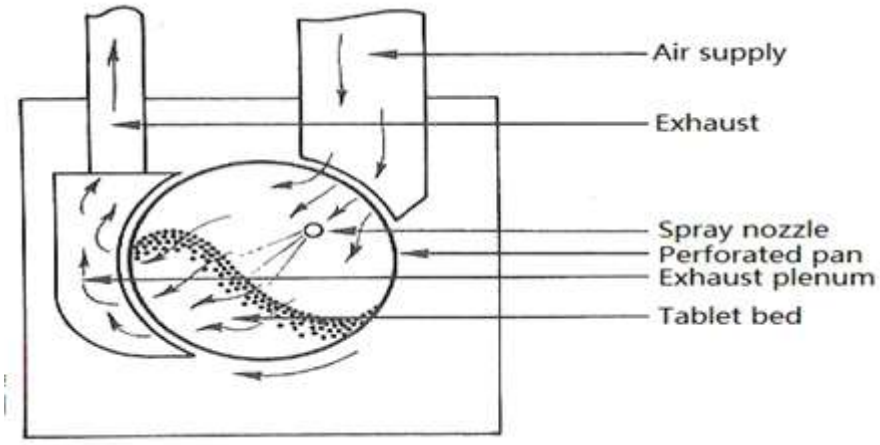

Fig. 1 Conventional pan systems**:**

a. Pellegrini pan

- Has a baffled pan and diffuser for uniform distribution of drying air.
- It is enclosed and automated.

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Fig 2. Pellegrini pan

b. Immersion-sword system:

- Drying air is introduced through a perforated metal sword immersed in the tablet bed.
- The drying air flows upward through bed
- Coating solutions are applied by an atomized spray system directed onto the tablet bed surface.

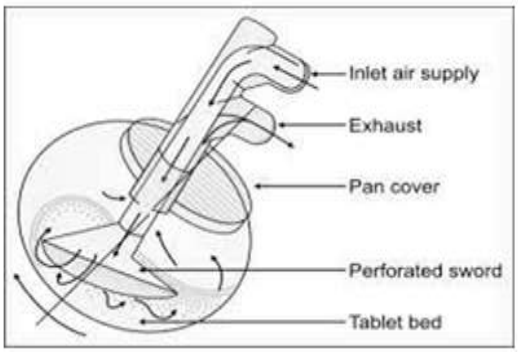

Fig 3. Immersion-sword system:

B. Perforated pan system:

It consists of a Perforated or partially perforated drum that rotates on its horizontal axis in an enclosed housing.

a. Accela-Coataand Hi-coater system

Moist air is channeled into the drum, flows through the bed, and is released through holes in the drum.

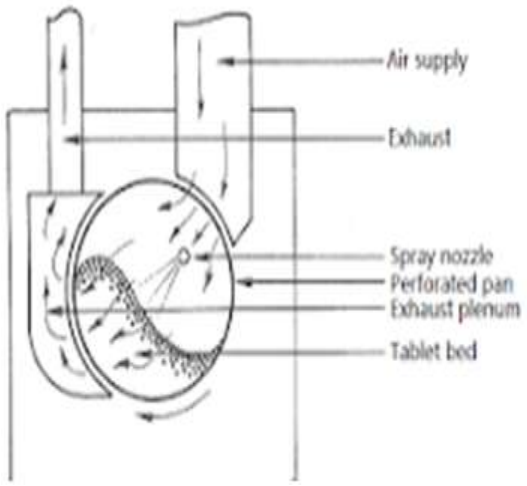

Fig 4. Accela cota system

b. Driacoater:

- Introduces drying air through hollow perforated ribs located inside periphery of the drum.
- As the coating pan rotates, ribs dip into tablet bed
- Drying air passes up through and fluidizes the tablet bed
- Exhaust is from the back of the pan.

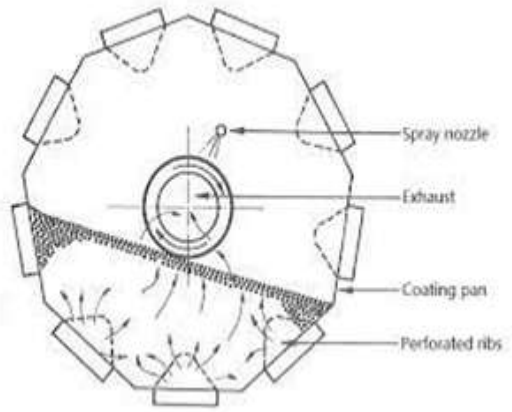

Fig5-Driacoater

C. Fluidized bed (Air suspension system):

- These are highly efficient drying systems
- Fluidization of tablet bed is achieved in a columnar chamber by the upward flow of drying air.
- The airflow is controlled so that more air enters the center of the column, causing the tablets to rise in the center

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- The movement of tablets is upward through the center of the chamber. They then fall towards the chamber wall and move downward to re-enter the air stream at the bottom of the chamber.
- Coating solutions are continuously applied from a spray nozzle located at the bottom of the chamber or are sprayed onto the top of the cascading tablet bed by nozzles located in the upper region of the chamber.

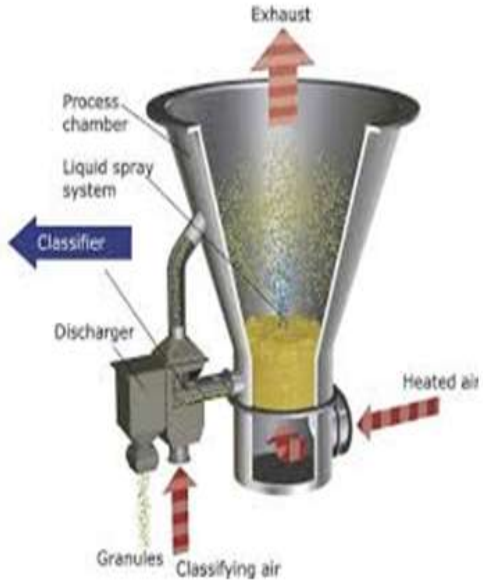

Fig 6 Fluidized bed (Air suspension system):

VARIOUS KINDS OF TABLET COATING

1. Sugar Coating

To hide the bitter taste of the tablets, sugar coating was used. Sugar coating is applied to bitter medications to cover up their taste. It also gives tablets a nice appearance. The following are the steps that make up the sugar coating process

Sealing: It provide moisture barrier to tablet and hardens it.[17]

Sub coating: This step is done to round the edges and increase the tablet weight.[18]

Grossing/Smoothing: This fills up the imperfection of subcoating and increases the tablet size to predetermine dimension.

Coloring: This gives the final color to the tablet.

Polishing: This is done to obtain desired luster.[19]

Film Coating

As Coating: Due to the lengthy nature of the sugar-coating process, film coating technology has taken its place. To create a thin, consistent film on the tablet surface, a rotating tablet bed is sprayed with a polymer, pigment, and plasticizer solution. The selected polymer is mostly determined by the intended release rate or the intended site of medication release (intestine or stomach). [20]

Dip coating:

- In this, cores to be coated are a held in a suitable device eg: baskets
- Dipped into coating solution and then dried taking care to prevent adherence to one another.
- For obtaining more perfect or heavier coats the dipping and drying steps may be repeated several times one after another.
- Several dipping arrangements are obtainable, amongst them the sophisticated devices comprise tiny suction tubes, which hold the individual tablets apart until drying is accomplished.
- Before proceeding to coat additional tablets or begin recoating cycles.

Enteric coating

An enteric coating is a type of barrier that regulates where oral medication is absorbed in the digestive system. Since the name "enteric" refers to the small intestine, enteric coatings stop medication from releasing before it gets to the small intestine. At low pH, the enteric coated polymers continue to unionize and remain insoluble. However, as the pH rises in the gastrointestinal tract, the polymer swells or becomes soluble in the intestinal fluid because the acidic functional groups can ionize

Enteric Material Should have following properties-

- Resistance to gastric fluids.
- Ready susceptibility or permeability to intestinal fluids.
- Stability with coating composition and drug substrate.
- Stability alone and in coating solution.
- Formation of continuous film.
- Nontoxic, Low cost.
- Ease of application without special equipments.

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- Ability to be printed or to allow film to be applied to debossed tablets.

Need of enteric coating:

- To protect the stomach from the drug
- To protect the drug from the stomach
- To protect the acid liable drugs from the gastric fluid
- To forbid gastric distress or nausea due to irritation from a drug.[21]

Evaluation of coated formulation

1. Hardness and friability

For tablets to withstand mechanical shakes during the manufacturing, packing, and shipping processes, they must meet certain requirements for hardness, strength, friability, and resistance. It is an important component that impacts the tablet's disintegration rate, which rises with increasing hardness, as well as the tablet's crushing strength. Tablets are subjected to constant mechanical shocks and aberrations throughout the production, packing, and delivery processes. Tablets that are under stress may exhibit aberration, capping, or even shattering. Therefore, it's critical that tablets be made in a way that makes them resistant to stress. Friability tests must be used to assess tablets in order to track their sustainability and resistance.

2. Uniformity of weight

The degree of uniformity in the amount of the drug substance among dosage units is known as "uniformity of dosage unit." The drug-substance content should be within the range around claimed label in a batch to maintain and validate consistency of dosage units. An individual or a portion of a dose of the drug in a respective unit of the dosage form is termed as a dosage unit. Weight variation and content uniformity are two methods for demonstrating uniformity of dosage.

3. Disintegration time

According to pharmacopoeial standards (Indian Pharmacopoeia, British Pharmacopoeia, and USP), disintegration is an essential test for evaluating disintegration capability of granules, tablets, capsules, etc. This test evaluates a drug-dosage form for quality and performance via determination of time taken by the formulation to disintegrate completely. For example, if the capsule-shell gelatin does not obey pharmacopoeial quality parameters or tablets are highly compressed, then disintegration time is reported to be elevated.

4. Stability testing

Stability testing is a complex set of events considering expertise, time-effectiveness, and cost-effectiveness for maintaining safety, efficacy, and quality of formulation, which is understood as stability testing of pharmaceutical products. Stability testing is important for guarding the manufacturer by promising fitness and reliability of the product in the market with respect to all related attributes and patient compatibility for which the products are designed. Conducting additional tests for 3 months at 50C/75% RH and raising accelerated-testing duration from 6 to 12 months are considered under the specific changes required for global testing.[4]

Tablet coating defects-

Various defects in tablet coating, their causes and remedial actions to be carried out to prevent such defects [22] are listed out in Table 2.

S.N	Tablet coating defect	image	Causes	Corrective actions
1.	**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

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2.	**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 plasticize	Lower the plasticizer concentration. Use a plasticizer with a high molecular weight
3.	**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.
4.	**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.
5.	**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 Thethermal expansion characteristics of the coating and the core are different Overheating	Use polymeric blends of polymers of low molecular weight Mineral excipients should be avoided Do not

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			causes core expansion The coating has a lower mechanical strength An insufficient coating formulation Inadequate plasticization or excessive pigmentation	overheat the tablet's core Use a coating that has adequate mechanical strength Use the right coating formulation
6.	**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
7.	**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

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8.	**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
9.	**TWINNING:** It's a coating defect that causes tablets to stick together, particularly when two tablets are stuck togethe		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
10.	**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

II. CONCLUSION:

There are several uses for coating solid dosage forms, but managing the release profile and affecting the bioavailability metrics of active pharmaceutical ingredients (APIs) is of utmost significance. Coatings protected the gastrointestinal tract, masked off off-putting flavors, and preserved active chemicals. To improve product quality, a variety of coating techniques are used, each with advantages and disadvantages of their own. Coverage governs the bioavailability of the medicine and is administered in a dosage form that

is completely functional. But flaws could occur during coating, which could reduce the efficacy and acceptability of the product.

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