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A Review: Film Coated Tablets

Ankita Madhavrao Dasalkar, Prof.V.S.Munde
Dr.Babasaheb Ambedkar Marathawada Universityaurangabadmaharashtra.
Bachelor of pharmacy
B.Pharm Seven Semester
Shri Dhaneshwari Manav Vikas Mandalsdr.Vedprakashpatil Pharmacycollege,Aurangabad.

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ABSTRACT :
Pharmaceutical film coating is considered a key part in the production of solid pharmaceutical dosage forms since it gives superior organoleptic properties products. In addition, it can improve the physical and chemical stability of dosage forms, and modify the release characteristics of the drug. Several troubleshooting problems such as twinning mottling, chipping, etc., may arise during or after or even during the shelf life of the film coated dosage forms. These troubleshooting problems may be due to tablet core faults, coating formulation faults and/or coating process faults. These problems must be overcome to avoid unnecessary product problems. Film coating as well as other parts of the pharma-ceutical technology is subjecting to continuous innovation. The innovation may be at different levels including pharmaceutical excipients, processes, software, guidelines and equipment. In fact, of particular note is the growing interest in process analytical technology, quality by design, continuous coating processing and the inclusion of new ready for use coating formulations. In this review, we tried to explore and discuss the status of pharma-ceutical film coating, the challenges that face this manufacturing process and the latest technological advances in this important manufacturing process.
Keywords: film coating, troubleshooting, advances, functional

I. INTRODUCTION :

Oral solid dosage forms are considered the most convenient dosage forms (DFs) available in the pharmacy. Their production was introduced over centuries ago. These DF have several advantages including their relatively easygoing and convenient manufacture, coupled with high patient compliance.[(1)] Tablets, the most relevant member of this class, have been improved in the last decades by introducing techniques such as tablet coating, double compression, and osmotic systems to achieve controlled and targeted release. Several techniques are available to achieve coating.[(2)]The most common techniques are sugar coating film coating, microen-capsulation, and compression coating.[(3)] Sugarcoating is a conventional old method used to coat FDs. In fact, it involves several individual applications of various coating formulations such as sealing of the tablet core (using a thin layer of film coat), sub-coating, smoothing, colouring, polishing, and printing. These steps result in tablet weight gain of about 50 to100% which is considered time-consuming, increases the final coast of the manufactured DF, and negatively impacts its swallowing.[(4)] Compression coating, also known as press coating or dry coating, has been developed to produce tablets containing incompatible drugs and to develop modified-release products. It involves the compaction of the dry coating excipients around tablet cores that have been produced on the same machine. It requires the use of special tableting machines which means further capital investment by the pharmaceutical industry. Therefore, it is considered a complex method and has not been commonly adopted as a method to coat tablets. Accordingly, it is usually exploited when the drug is heat and water sensitive since it eliminates the use of organic or aqueous solvents. Recently compression coating has been found useful to develop and produce novel drug-delivery applications such as controlled release DFs.[(5)]Film coating (FC) is considered the most popular and versatile method. FC is a modern and widely spread process for coating oral solid DFs in the pharmaceutical and food industries. The process of FC involves the spraying of a thin, but uniform polymer-based formulations onto the surface of solid DFs including tablets, capsules, pellets or granules. It can be classified into two specific classes; nonfunctional FC which is used to change tablet appearance, organoleptic properties, swallowing properties, and to protect tablets from the negative effect of the environment such as humidity, oxidation, and light effects. On the other

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hand, functional FC can be used to modify or delay drug release as well as the aforementioned benefits in the non-functional coating.Microencapsulation is a modified form of FC. In fact, the only difference relay in the size of the particles to be coated and the methods by which the coating is achieved. This rapidly expanding process is based on either mechanical or physicochemical methods or techniques. The mechanical techniques include air-suspension, multi-orifice centrifugal, and modified spray-drying techniques, while the physicochemical methods involve coacervation-phase separation, which needs that the drug to be coated is dispersed in a suitable solution of the Polymer.[6,7]In this extensive review, we sought to explore the status of pharmaceutical C, the challenges that face this manufacturing process, and the latest technological advances in this process.

CRITERIA FOR POLYMERS USED IN FILM COATING.[8]

SOLUBILITY:

For conventional film coating the polymer should have good solubility in aqueous fluids to facilitate the dissolution of active ingredients from the finished dosage form. However, where a modified release action is required then a polymer system of low water solubility or permeability will be chosen

VISCOSITY:

In general polymers should have a low viscosity for a given concentrations. This will permit the easy trouble free spraying of their solution in industrial film coating equipment.

PERMEABILITY:

Film coating can be used to optimize the shelf life of tablet preparation as some polymers are efficient barriers against the permeability of water vapor or other atmospheric gases. These properties vary widely between the individual polymers.

MECHANICAL PROPERTIES:

A particular polymer chosen for a film coat formulation must be one week adequate strength to withstand the impact and abrasion encountered in normal handling.[9,10] Insufficient coating strength will be demonstrated by the development of cracks and other imperfections in the coating. It should be mentioned that the polymer chosen must also comply with relevant regulatory and pharmacopoeia requirements current in the intended marketing area.

Ideal requirements of film coating materials:

i)Solubility in solvent of choice for coating preparation
ii) Solubility requirement for the intended use
e.g. free water-solubility, slow water solubility or pH -dependent solubility
iii) Capacity to produce an elegant looking product
iv) High stability against heat, light, moisture, air and the substrate being coated
v) No inherent colour, taste or odor
vi) High compatibility with other coating solution additives
vii) Nontoxic with no pharmacological activity
viii) High resistance to cracking
ix) Film former should not give bridging or filling of the debossed tablet
x) Compatible to printing procedure.[11]

TABLE NO : 01 MATERIALS USED IN FILM COATING

Sr. No	Material	Types	Uses	Example
1	Film Former	Enteric Non Enteric	To control the release of drug	Hydroxy Propyl Methyl Cellulose (HPMC), Methyl Hydroxy Ethyl
2	Solvents	**.....**	To dissolve or disperse the polymers	IPA and Methylene chloride
3	Plasticizer	Internal Plasticizing External Plasticizing	It Pertains to the chemical modification of the basic polymer that alters the physical properties of the polymer.It	Glycerol, Propylene glycol, PEG 200-6000 GradesDiethyl phthalate (DEP), Dibutyl hthalate(DBP) and Tributylcitrate

International Journal of Advances in Engineering and Management (IJAEM)
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			incorporated with the primary polymeric film former, changes the flexibility, tensile strength, or adhesion properties of the resulting film	
4	Colourants	Inorganic materials Natural coloring agents	For light shade: concentration of less than 0.01% may be used For dark shade: concentration of more than 2.0% may be used	Iron Oxides Anthocyanins, Caramel, Carotenoids,
5	Opaquant Extenders	.....	Formulations to provide more pastel colours and increase film coverage	Titanium dioxide, silicate (talc &aluminum silicates), carbonates(magnesium carbonates) 3

Importance of Film Coating.[12]

• To protect against environmental factor like sunlight, temperature, moisture and air.
• To ease to swallow.
• To mask taste and odour.
• To increase shelf life.
• To enhance the image of brand.
• To ease in formulation.
• To strength of the dosage form.
• To protect drug for GIT environment.
• To control in release of drug.

Advantages of Film Coating :

1. Short production time and high degree of automation. The use of a film coating process can reduce or avoid dust in the workshop, which is conducive to environmental protection and labor protection;
2. The quality of the film coating is much lighter than that of the sugar coating, thus saving material and reducing the weight of the total tablet;
3. Due to the large number of film-forming materials and auxiliary materials, it has been carefully designed to make film garments with various characteristics, such as gastric film, enteric film, sustained release film, controlled release film, etc., which broadens its technical application range;
4. Because the film-forming agent and most auxiliary additives are polymer materials with excellent physical and chemical properties, they are non-toxic and tasteless, and greatly improve the dissolution rate, bioavailability and effective period of the drug;
5. The film-coated tablets are small in size and smooth in form, so it is easier for children and elderly patients to swallow;
6. Film coated tablets have no restrictions on patients with diabetes and patients with sugar, which expands the scope of use of patients.

Disadvantage of Film Coating.[12]

• Coating generates various coating defeats.
• Change in surface smoothers.
• Increase cost of dosage form.
• In few case change in properties of formulation.

Classification of Film Coating

FC can be classified based on its intend use in the functional and non-functional coating.

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1.Non-Functional FC

Along with the tablet shape and size, plays a key role in improving patient compliance since it impacts the final appearance and organoleptic properties of the produced tablets which are considered essential aspects of the brand image.[13–14] Moreover, FC plays a very important role in helping elderly patients suffering from dysphagia since swallowing can be facilitated by the presence of a film coat on the DF.[15] The US FDA has reported that the presence of a FC can either increase or assist tablet mobility compared with a non-coated tablet of the same shape and size.[16] In addition, many APIs have a disagreeable bitter taste, which represents a serious challenge during the development of oral liquid products, particularly for pediatric patients. However, this inconvenience can be overcome by a simple FC of the conventional oral slid DFs. The polymer coat creates a physical barrier between the taste buds and the API, which minimizes the opportunity for the solubilized drug to interact with these buds. However, for chewable tablets, more sophisticated FC approaches may be required, which can include coating the API crystals with the design intent to retard dissolution in the oral cavity without altering the desired dissolution pattern in the gastrointestinal tract (GIT) to avoid any negative effect on drug bioavailability. For example, the API can be coated with suitable polymers or copolymer to form nano or microcapsules, which can be used to form chewable taste-masked granules (Table 2).[17,18]

2.Functional FC

As we mentioned earlier in this review, functional FC is mainly used to add a new added value to the produced products. These values may include one or more functions such as improving the stability of the product and modifying its release pattern to produce drug targeting products.

TABLE NO : 02 Some of the Most Used Components in Functional and Non-Functional FC Function

Sr.No	FUNCTIONS	MATERIAL NAME
01	Functional Film Forming Polymer	Cellulose Acetate Phthalate Hydroxy Propyl Methyl Cellulose Phthalate Cellulose Acetate Trimellate Ethyl CelluloseMethacrylic Acid Copolymer Shellac
02	Non-Functional Film Forming Polymer	Hydroxy Propyl Methyl Cellulose Hydroxy Propyl Cellulose Polyvinyl Pyrrolidone Polyvinyl Alcohol High Molecular Weight Polyethylene glycol
03	Solvent or Vehicle Plasticizers	Water, Ethanol, Methylene Chloride , Propylene Glycol, Polyethylene Glycols, Diethyl Phthalate, Fractionated Coconut Oil, Castor Oil
04	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)

*** Product Stabilization**

Product stability is considered one of the most important goals in pharmaceutical developments. Accordingly, a scrutinized effort should be carried out to achieve stable products for the longest time. This includes using suitable pack design, desiccants, and specialized moisture protective FC polymers (Table 2).[19]This step is particularly appropriate to protect the bulk product before its packaging or during transit if the packaging is performed at a remote facility. In addition, it may help the product to withstand the moisture environments after opening the bottle especially when the product is to be repackaged in

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dose administration aids.[20,21] Recently, Burke et al reported that using moisture protection barriers may stabilize a water-sensitive API. Also, the use of such barriers could decrease potential negative interaction with another API in a fixed-dose combination tablet.[22] Evidently, FC procedures based on aqueous formulation can still show serious problems and threats toward moisture-sensitive APIs. These challenges and problems could be fixed involving organic solvents in the coating formulation. Nonetheless, the manufacturing process must be conducted in an explosion-proof premises and equipment. In addition, the final coated dosage SF must comply with ICH Q3C (R6) guidelines regarding current residual solvent.[23–25] Alternatively, a dry FC technique may be applied to avoid the dissipation of organic solvents in the environment.[26] Regarding photo-stabilization of photosensitive API, the use of an opacifying agent, such as titanium dioxide, in the coating formulation would enhance the capacity of the FC to protect the drug from light degradation effect, especially, when the film possesses a contrast ratio values higher than 98%. This could be achieved when the film thickness of the coat is close to 150µm and using a coating suspension containing about 30% TiO2.[27] Another study was conducted by Mukharya et al to assess the effect of FC on the photostability of highly photo-sensitive antihypertensive products. In this study, the percentage level of FC was optimized by directly exposing core tablets to three levels of FC, 1% w/w, 2% w/w, and 3% w/w. According to the outcome of this study, 2% w/w FC level was found to be appropriate to protect the API in the core tablets after being exposed to a light source as per Option-2 of ICH Q1B.[28,29]

*** Modified Release Coating Functionalization**

Modifying drug release is a common practice in DF design which can be accomplished using FC. Two types of modified release DFs are described by the USP, those that are enteric-coated and those that are extended-release. Delayed-release products which often designed to prevent drug release in the upper part of the GIT. FDs is designed to produce this type of DF are commonly named enteric coatings.[30] On the other hand, FCs that are designed to prolong drug release over a long period or to reduce the drug regimen are commonly named sustained or extended release FCs.[31]

2.1. Delayed-Release FC

Delayed or enteric-coated DFs are often achieved using pH-sensitive polymeric coats capable to delay the release of certain APIs, either to protect the drug against the acidic environment in the stomach (ie proton pump inhibitors) or to protect the stomach against the irritant effect of the drug due to its chronic use as non-steroidal anti-inflammatory drugs like diclofenac sodium.[32–34] Usually, polymers used to achieve enteric release bear carboxylic moieties on their main chain making them insoluble at pH less than 5 (Table 1). These acid-resistant polymers have been commonly used to forbidden drug release at pH 1.2. On the other hand, they show a significant increase of solubility at a pH higher than 5.5, thereby bypassing the stomach and releasing the drug in the small intestine.[35,36] Another type of delayed-release product is used to achieve colon-specific drug delivery. For example, 5-aminosalicylic used to treat irritable bowel disease, has unwanted side effects along with the GIT. This can be achieved by coating the tablets or pellets using polymers soluble at pH higher than 7. Certain brand products use two pH dependant layers, with the first one soluble at pH higher than 5.5 which releases part of the API in the small intestine, while the second layer dissolves at pH higher than 7 in the colon. This design could be realized involving either film coating or by preparing two different film-coated granules as was reported by Howdenet.al.[37,38] The designed formulation was composed of two proton pump inhibitor granules with the first ingredient released within two hours after dose administration providing day-time therapy for gastroesophageal reflux disease (GORD); while the second ingredient released within 6 hours after dose administration and addressed overnight GORD. Based on the variability of GIT pH recognized within the general population (especially with colonic-pH), the efficiency of colon-specific drug delivery systems involving pH alone has been extensively discussed.[39] Accordingly, many alternative approaches have been suggested. Resistant starch or high-amylose maize starch can be mixed with anionic copolymers based on methacrylic acid and methyl methacrylate to promote reproducible colonic-release. This technique depends both on colonic-pH and selective microbial degeneration of the starch in the colon.[40] Despite of dietary conditions, this technique exhibited persistent release at the ileocecal junction or within the colon.[39] A FC approach employing an outer film of methacrylic acid and methyl methacrylate copolymers and an inner alkaline buffered film was also reported. This approach ensures that the inner alkaline film promotes the dissolution of the polymer which

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Volume 5, Issue 2 Feb. 2023, pp: 462-474 www.ijaem.net ISSN: 2395-5252

permits targeted release at the ileocecal junction.[8,41–44)]

2.2 . Controlled Release FC

Sustained-release oral DFs were developed to decrease the number of dosage regimens, especially when the drug requires a reasonable constant blood level over a prolonged period. In addition, it also has been used for those APIs that need to be given in high doses, but at the same time a conventional immediate release is likely to cause undesirable ulceration. This can be accomplished by different techniques such as increasing the particle size of the drug, enclosing the drug in a suitable matrix, complex formations between the API and ion-exchange resins, and coating the API or the DF that contain the API.[(45)] The API dose in a multi-particulate (MP) delivery system is dispersed across the whole GIT. Accordingly, this represents an advantage over the single unit coating since failure of a few units will be significantly less dangerous than the failure of a single-unit tablet or capsule which may cause dose dumping. For this purpose, MPs, nonpareil approach is available. The nonpareil sugar particles which are coated with a FC that contain the AP and then various functional and non-functional film seal coats are applied over the particle to achieve the desired release pattern including; MR release profiles, enteric and/or targeted release, and/or pulsatile release. A recent review summarised the different MP approaches, eg, swelling/rupturing, dissolution and/or erosion, and modification of the intrinsic permeability of the FC.[(46)] Many different polymers have been evaluated to coat MP systems; some of these include starch acetate,[(46)] ethyl cellulose[(47)] and Eudragit RS, RL, andS.[(48)] In addition, the impact of the type of FC technique (aqueous or organic) on the performance of the polymer and the release profile of the resultant product was also investigated by Lecomete et al The outcome of this study revealed that FC technique significantly affects the film microstructure and, thus, the release mechanism and profile from pellets coated with polymer blends.[(49)]Another way to control drug delivery and achieving prolonged action is accomplished by the use of a pulsatile delivery system. This control is usually achieved by the layering of nonpareil cores with an active layer, a swelling layer comprising binders, disintegrant and an insoluble, water-permeable polymeric FC.[(50.47)]

Film Coating Methods :

1.Organic solvent-based film coating:

Although the use of organic solvent is not preferred,film coating with hydrophobic or lipophilic polymers requires the use of organic solvents due tothe low aqueous solubility of coating materials. The highly hydrophobic polymers are beneficial asmoisture-protective coating polymers as they can reduce the water vapor permeability of the final filmby preventing the movement of water molecules [[51]]. In addition, coating process using organic solventscan also reduce drug degradation by hydrolysis. Therefore, organic solvent-based coating is usefulfor moisture sensitive drugs. The rate of evaporation of the solvent is crucial for the quality of finalproduct and many variables including temperature, atmospheric pressure, and air movement should beadjusted to optimize the evaporation rate [52]. Despite of pharmaceutical needs, organic solvent-basedcoating has many critical limitations because of potential toxicity of residual solvents, flammability,and environmental safety issues [52]. Even with a proper ventilation facility, it is difficult to completelyremove organic solvent vapors from the coating room, increasing the risk of toxicity and explosion.Environmental and regulatory issues can increase the production costs.

2.Aqueous film coating :

is a widely used film coating method in currentpharmaceutical practice. It has many advantages over organic solvent-based coatings in termsof operator safety, environmental pollution, and risk of explosion. Despite these benefits overorganic solvent-based coating methods, aqueous coating also possesses certain drawbacks includingenergy- and time-consuming water evaporation process, longer processing time, validation of coatingdispersion to control microbial presence, and potential activity loss of certain drugs caused by wateror high coating temperature [53]. In addition, preparation of an aqueous coating solution withwater-insoluble polymers requires the addition of a suitable suspending agent or plasticizer for ahomogeneous coating solution [52]. Although aqueous film coating has some limitations, it can avoidthe safety issues associated with organic solvent-based coating, and thus it is still widely used in thepharmaceutical industry. There are continuous efforts to reduce the processing time and improveproductivity by process automation, process validation, and development of more efficient equipment,such as side-vented perforated coating pans and fluidized bed equipment [54].

International Journal of Advances in Engineering and Management (IJAEM)
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3.Solvent-free coating:

The use of solvents and heat exposure in the coating process can increaseproduct instability, processing cost, and risk of environmental and safety hazards [55]. Therefore,solvent-free coating methods have been actively pursued to overcome the drawbacks of solvent-basedcoating. Solvent-free coating can reduce the process time and cost by avoiding expensive andtime-consuming processes of solvent disposal [56]. Furthermore, since it does not require drying inmost cases, solvent-free coating is applicable to heat-sensitive drugs [56]. Solvent-free coating includesvarious technologies such as compression coating, dry powder coating, electrostatic spray powder coating, and photocuring coating [52,57,58]. Recently, injection molding coating and hot melt coatinghave also been proposed as dry coating processes that do not require solvent [55,59-60]. In the injectionmolding coating process, the upper and lower surfaces of tablets are coated in two steps using avertical injection molding unit. It is important to choose the right polymer because quality variesdepending on workplace humidity and polymer properties. As high temperature (over 80◦C) is usedfor coating, it is important to examine the surface conditions of coated tablets after cooling [55,59].Hot-melte high process temperatures depending on the melting point of coatingmaterials may aff ect the stability of the tablet ingredients [61]. Like injection mold coating, manyvariables may occur depending on excipi characteristics [62,63]. Spray congealing or spray coolingis also a melting-based method that transforms a melt into spherical solid particles. This method hasadvantages including the absence of solvent, low cost, applicability to hygroscopic and water-sensitivesubstances, and the ability to obtain spherical free-flowing microparticles for tableting or capsulefilling without the need of other downstream processes [64,65]. Spray congealing technology includesthree steps (feed, atomization, and solidification stages) [66]. The first step involves the preparationof the fluid consisting of the molten carrier and drugs. As drugs may be dissolved or dispersedinto the molten carrier, it is important to keep the fluid homogeneous for a uniform drug loading.During the atomization step, the molten fluid stream breaks up into small droplets that are quicklysolidified upon cooling to produce the solid microparticles. In this process, viscosity is a critical factordeciding the viability of spray congealing and the size of produced microparticles [64,65]. In general,spray congealing is not suitable for highly viscous molten mixtures that may clog the feed tube oratomizer[65].Although solvent-free coating may overcome some issues associated with solvent-based coating,the requirements for specific coating conditions, equipment, and coating materials limit wide application of solvent -free coating in the pharmaceutical industry.(53)

4.Electrostatic Dry Coating :

For the first time, an electrostatic dry powder coating process was developed in a pan coater gadget system for solid dosage forms. This process helps to provide the tablet with a smooth surface bed, excellent coating uniformity, and release at a particular solvent grade.The electricity coating method played a very important role in several manufacturing industries such as paint technology, food technology, metal coating process, and pharmaceutical industries to the coating of solid dosage forms. The principle involved in the electrostatic dry coating process, directly spreading of particle and polymer mixture on the surface of tablet bed without the addition of solvent and heating will be applied until its form a film over the surface of tablet's. [67], [68]

5.Super-Cell Coating Technology :

Supercell coating technology is an amazing coating technology of the cutting-edge tablet that can withstand extremely hygroscopic materials and friable coating ingredients can be deposited into it. Sometimes this technology gives nonhomogenous output due to imperfections and inconsistency. The process involved in the supercell coating technology is that edges of tablets are ground off and corners of the tablet are not coated with the same thickness applied in tablet faces otherwise tablets can be stacked in the rotating pans and airflow cannot pass throughout the pan. That's why the modified release of coating is limited due to the deposition of the coating materials [69]. Supercell coating technology was invented by Niro Pharma Systems which helps with various problems employing a small modular design.

Features of Super-Cell coating technology

1) Coating of multiple layers over the surface bed of solid dosage forms.
2) Modular designs are easily flexible.
3) Coating can be continuous and easily adaptable.
4) Production capacity is more & can be 6 cells coats up to 120mg
5) Can be used in the R & D department withstand of the minimum batch size range 30mg
6) Much more accurate than other technology.
7) Having a low humidity process that is suitable for low moisture-sensitive materials.

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8) Enabling technology.
9) Friable tablets.

INSTRUMENTS USED IN FILM COATING TABLETS

1.Standard Coating Pan
2. Perforated Coating System
3.Fluidized Bed Coater

1.Standard Coating Pan :

Standard coating pan gadget includes a round steel pan set up on a stand particularly in angular position. the pan is 8-60 inches in diameter and is rotated by a horizontal axis by a motor. Hot air is sent to the pan and the surface of the tablet bed. And is exhausted through ducts position through the front of the pan. Coating solutions are delivered to the drug by spraying or spraying the rotating tablet on the bed. By ladling or spraying the coating solution is applied to the tablet bed. Use of an atomizing system to spray the liquid coating material onto the tablets produces a faster more even distribution of the solution or suspension. spraying can significantly reduce the drying time between solution application in sugar-coating processes and allows for continuous application of the solution in film coating

2.Perforated Coating system :

Perforated Coating system is used in two cases totally perforated or partially perforated drum, which rotates in an enclosed housing on its horizontal axis. The drying of coating material by perforated coating system is better as compared to other conventional methods. This system makes a huge compensation in time.

3.Fluidized Bed Coater :

Fluidized Bed Coater is a highly efficient drying system. Fluidization of the tablet mass is achieved in a columnar chamber by the upward flow of the drying air. The air flow is controlled to draw more air in the middle of the column, which causes the tablet to rise in the center. In some units a small column is used to control the movement of the tablet inside the main column. Coating solutions are applied continuously to the bottom of the chamber with a spray nozzle located above the chamber of the bed.

Tablets Coating Defects :

1. Picking and sticking.[68]
Cause: it creates overly wet bed where adjacent tablets stick together and break apart
Remedies: Increase in the dying air temperature in the preheating stage.

2. Blistering
Cause: Entrapment of gases in the film due to overheating during spraying
Remedies: Milder dying condition are warranted in this case.

3. Mottling.[68]
Cause: Degradation of the production
Remedies: Prepare coating solution properly

4. Orange peel effect.[69]
Cause: Inadequate spreading of the coating solution.
Remedies: Thinning the solution with additional solvent.

5. BloomingCause:
Mostly due to plasticizer Coating becomes dull immediately or long time

6. Chipping.[70]
Cause: Decrease in fluidizing air
Remedies: Careful not to over dry the tablets in the preheating stage.

7. Twining
Cause common problem
Remedies: increase the pan speed

8. Pitting
Cause: Temperature of the tablet core is greater than the melting point of the material used in the formulation
Remedies: Control of temperature of tablets core.

9. Colour variation
Cause: Variation alteration of the frequency and duration of the spray zone Remedies: Reformulate with different plasticizers.[68,71]

Evaluation Parameters for Film Coating Tablets :

1.Weight variation
Twenty tablets are weighed individually and the average weight is calculated. The individual tablet weights are then compared to the average weight.

2.Thickness
The thickness of individual tablets may be measured with a micrometer, which permits accurate measurements and provides information of the variation between tablets.

3.Hardness
Hardness was determined by taking six tablets from each formulation, using a Monsanto Hardness Tester.

4.Friability
It is usually measured by the use of the Roche friabilator. A number of tablets are weighed and placed in the apparatus where they are exposed to rolling and repeated shocks as they fall 6 inches in each turn within the apparatus. After four minutes

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of this treatment or 100 revolutions, the tablets are weighed and the weight compared with the initial weight. The loss due to abrasion is a measure of the tablet friability.

5.Disintegration

The disintegration test is carried out using the disintegration tester which consists of a basket rack holding 6 plastic tubes, open at the top and bottom, the bottom of the tube is covered by a 10-mesh screen. The basket is immersed in a bath of suitable liquid held at 37oC, preferably in a 1L beaker.

Pharmaceutical Application of Film Coating

1.Modified Drug Release

In many cases, modified drug release is beneficial for improving drug efficacy and patientcompliance or prolonging the duration of actions. [72]Therefore, tablet film coating with various polymers is actively pursued to achieve modified drug release by controlling the rate and/or sites ofdrug release.

2.Sustained Drug Release

Drug release rate can be controlled by physicochemical properties and the amount of polymers used for surface coating [73,74]. It is also controlled by altering the thickness, tortuosity, and permeability of the coating layer [75]. Coating materials for sustained drug release are usually waterinsoluble and pH-independent, and are exemplified by ethyl cellulose, polyvinyl acetate, and polymethacrylate copolymers [76,77]. These polymers have good film forming properties and mechanical strength, making them suitable for sustained drug

3.Improved Drug Stability

The stability of APIs or drug products can be altered by external environmental factors such as temperature, humidity, and light, as well as compatibility between excipients and APIs. Moisture can degrade drugs through hydrolysis and cause instability issues during storage [78]. Moisture-absorbeddrug products can swell, crack, and dissolve inside the package, causing significant changes in productappearance and negatively affecting the shelf-life of the drug product [78]

4.Taste Masking

Unpleasant taste is a major hurdle to ensure patient compliance, particularly in pediatric and geriatric populations. Among various tastes, bitterness is the most repellent. Thus, masking bitter taste in oral dosage forms is a key parameter to improve patient compliance and therapeutic efficiency [79]. Optimized oral dosage forms should reliably hinder the release of bitter drug molecules in the mouth. However, taste masking should not negatively affect the bioavailability of drugs, or sensory awareness including mucosa irritation, roughness in the mouth, or hindered swallowing [80].

Marketed Preparation Of Film Coated Tablets :

Sr. No	Drug Name	Composition	Used As	Mfg by
1	CETRIZINE	Cetrizine	Hay fever	Newtech
2	Zelboraf 240mg	Vemurafenib		Roche
3	Tagrisso 80mg	Osimertinib	Small cell lung cancer	Tagrisso
4	Fycompa 4mg	Fycompa	Epilepsy	Eisai
5	Ramiven	Abemaciclib	Anti cancer	Lilly
6	Stylecystin 600	N-acetylcysteine	Bronchitis	Newtech
7	Myfortic	Mycophenolate sodium	Prevent rejection after kidney transplant	Novartis
8	Capreisa	Vandetanib	Anti cancer	Capresia

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