



INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Discussion on tablets with special emphasis on formulation and coating defects: A Review

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ABSTRACT

The majority of the research scientists have involved industry, academic liaison to propose to implement newer heights in tablet technology. Tablets and Capsules are unit the foremost usually used indefinite quantity forms everywhere the planet, due to patient compliance, flexibility in dosage regimen and designing of the dosage form. Tablet coating could be a common pharmaceutical technique of applying a skinny polymer-based film to a pill or a grain containing active pharmaceutical ingredients (APIs). Solid indefinite quantity forms are unit coated for variety of reasons, the most important of which is controlling the release profiles. Tablets are unit sometimes coated in horizontal rotating pans with the coating answer sprayed onto the free surface of the pill bed. The advantages of pill coating are unit style masking, odor masking, physical and chemical protection, protects the drug from the gastric environment, etc. There are unit numerous techniques for pill coating like sugar coating, film coating, and enteric coating. Recent trends in pharmaceutical technologies are unit the event of coating strategies that overcomes the varied disadvantages related to solvent-based coatings. In these latest technologies coating materials are unit directly coated onto the surface of solid indefinite quantity forms while not victimisation any solvent. This review deal in detail about processing problems in tablet formulation, history, recent tablet coating technique and remedies associated with the tablet coating.

Keywords: release profiles, dosage regimen, rotating pans, tablet bed, tablet coating, coating area and pharmaceutical technologies.

1. Introduction

Solid medicaments that are usually administered orally as powders, pills, cachets, capsules or tablets. These dosage forms contain a quantity of drug which is given as a single unit and they are known collectively as solid unit dosage forms, even in the case of sustained action preparations which, technically, contain the equivalent of several normal doses of drug. The stringent formulation requirements of modern medicaments, various advantages of tablet and capsule medication, adjoined with expanding health services and the commitment need for large-scale economic manufacture, have led to a steady decline in the prescribing of powders and pills. Tablets and capsules, on the other hand, currently account for well over two third of the total number and cost of medicines produced all over the world.^[1-3]

Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients. According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drugs or a mixture of drugs, with or without

diluents. They vary in shape and differ greatly in size and weight, depending on amount of medicinal substances and the intended mode of administration. It is the most popular dosage form and 70% of the total medicines are dispensed in the form of Tablet.

Almost all drug molecules can be formulated in a tablet and the process of manufacturing of tablets is very simple and is very flexible. Enteral route of drug delivery is the most widely utilized route of administration among all the routes for the systemic delivery of drugs. The main goal drug delivery system is to provide the therapeutic amount of the drug at the site of action as effective throughout the whole period of therapy and then maintain the desired drug concentration. The conventional dosage form produces a wide range of variation in drug concentration in the bloodstream and body tissues which leads to the reduction of drug effectiveness or increased incidence of side effects with subsequent undesirable toxicity and poor efficiency. The coating is a process by which an essentially dry, outer layer of coating material is applied to the surface of a dosage form to achieve specific benefits. The coating may be applied to a wide range of oral solid dosage forms, including tablets, capsules, multiparticulates and drug crystals. When the coating composition is applied to a batch of tablets in a coating pan, the tablet surfaces become covered with a tacky polymeric film. Before the pill surface dries, the applied coating changes from a sticky liquid to tacky semisolid and eventually to a non-sticky dry surface pans. Many solid pharmaceutical indefinite quantity forms square measure created with coatings, either on the external surface of the tablet or on materials dispensed within gelatine capsules. The pill ought to unleash the medicinal drug bit by bit and also the drug ought to be offered for digestion. The coating methods are often specially developed to manage how briskly the pill dissolves and wherever the active medication square measure to be absorbed into the body once intake. This review is an attempt to illustrate readers the overall process of tablet coating and its types, problems and remedies for various coating defects with their advantages and disadvantages etc.

2. Special Problem In Compressing Tablet Process^[4-9]

An ideal tablet should be free from any visual defect or functional defect. The recent advances in tableting technique in tablet manufacture have not reduced the problems, often encountered in the production, instead have increased the problems, mainly because of the complexities of tablet presses; and/or the greater demands of quality. Besides the extensive efforts of industrial pharmacist usually encounters number of problems during manufacturing. Majority of visual defects are due to inadequate fines or inadequate moisture in the granules ready for compression or due to faulty machine setting. Functional defects are due to inadequate formulation. Solving many of the manufacturing problems requires in-depth knowledge of granulation processing and tablet presses, and is acquired only through an exhaustive study and a vast experience. Here, we will discuss the imperfections found in tablets along with their causes and related remedies. Tablet processing problems can be due to the problem in the formulation or in the compression equipment, or both of them. Thus we can classify the problems into following types:

The defects related to the tableting process can be categorize into capping in which there is a partial or complete separation of the top or bottom of the tablet due to air-entrapment in the granular material. Lamination is the separation of a tablet into two or more layers due to air-entrapment in the granular material. Cracking occurs due to the rapid expansion of tablets when deep concave punches are used. The defects related to excipient can be explained like Chipping which results due to terribly dry granules, sticking is the adhesion of granulation material to the die wall, picking is the removal of material from the surface of the tablet and its adherence to the face of punch, binding problem is due to more amount of binder in the granules or wet granules. The defect related to more than one factor is mottling which is either due to any one or more of these factors viz. due to a coloured drug, which has different colour than the rest of the granular material, (Excipient- related); improper mix of granular material (Process-related); dirt within the granular material or on punch faces; oil spots by victimisation oily stuff. The defect related to machine is double impression which is due to free rotation of the punches, which have some engraving on the punch faces. Further, in this section, each problem is

described along- with its causes and remedies which may be related to either of formulation (granulation) or of machine (dies, punches and entire tablet press).

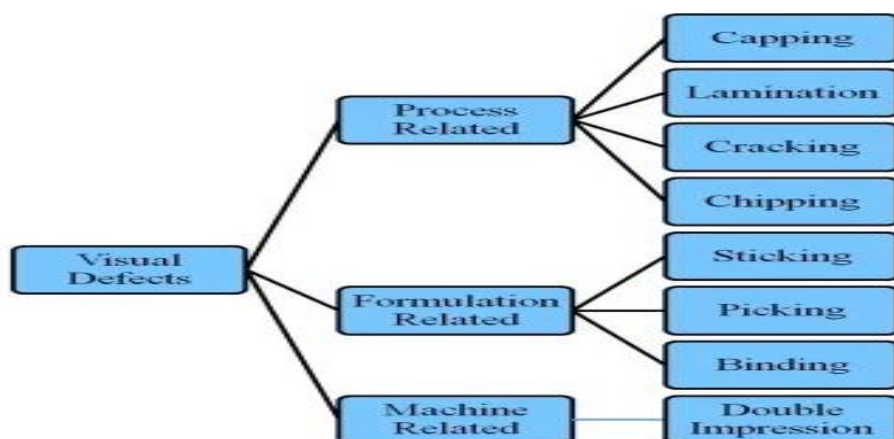


Fig.1 Classification of different types of Defects

CAPPING

‘Capping’ is that the term used, once the higher or lower section of the pill separates horizontally, either partly or fully from the most body of a pill and comes off as a cap, throughout ejection from the pill press, or throughout future handling. Capping is typically because of the air-entrapment in a very compact throughout compression and subsequent expansion of tablet on ejection of a tablet from a die.

The causes associated with capping are might be due to large amount of fines in the granulation, too dry or terribly low wetness content (leading to loss of correct binding action), not thoroughly dried granules. Capping may also results due to insufficient amount of binder or improper binder, insufficient or improper lubricant o sometimes the granular mass is too cold. Capping can be tackle using some or all fines through 100 to 200 mesh screen and moisten the granules suitably. We can also add absorbent substance like sorbitol, methyl- cellulose or PEG- 4000. We should dry the granules properly with somewhat increasing the amount of binder. Capping can be overcome by adding dry binder like pre-gelatinized starch, gum acacia, powdered sorbitol, PVP, hydrophilic silica or powdered sugar. Also by increase in the number of lubricating substance or amendment the kind of lubricating substance helps us to reduce the concern. The Causes and Remedies of Capping associated with Machine (Dies, Punches And Tablet Press) can be further categorize like poorly finished dies, deep concave punches or bevelled-edge faces of punches, lower punch remains below the face of die throughout ejection, incorrect adjustment of sweep-off blade and high turret speed etc. Possible remedies to avoid capping problems are viz. polish dies properly; investigate other steels or other materials, use flat punches, and create correct setting of lower punch throughout ejection. We can also keep changing sweep-off blade properly to facilitate correct ejection. Reduce speed of turret (Increase dwell time).

LAMINATION

Lamination is that the separation of a pill into 2 or additional distinct horizontal layers. The potential cause for lamination is air-entrapment during compression and subsequent release on ejection. The condition is exaggerated by higher speed of turret. The Causes and Remedies of Lamination associated with Formulation (Granulation) can be further specified viz. oily or waxy materials in granules, too much of hydrophobic lubricant, Magnesium-stearate etc. To overcome this concern several remedies like modify mixing process and add adsorbent or absorbent, use a less quantity of lubricating substance or amendment the kind of lubricating substance. The causes and remedies of lamination associated with machine (dies, punches and tablet press) are respectively categorize viz. fast relaxation of the peripheral regions of a pill, on ejection from a die, Rapid decompression. It can be resolve by the use of tapered dies, i.e. upper a part of the die bore has an outward taper of 3° to 5° and addition of pre-compression step, reduce turret speed and scale back the ultimate compression pressure etc.

CHIPPING

'Chipping' is outlined because the breaking of pill edges, whereas the pill leaves the press or throughout future handling and coating operations. It can be due to reason like incorrect machine settings, specially mis-set ejection take-off. The Causes and Remedies Of chip associated with Formulation (Granulation) can be respectively classified as sticking on punch faces, too dry granules, too much binding causes chipping at bottom and can be overcome with dry the granules properly or increase lubrication, moisten the granules to plasticize, add hygroscopic substances, optimize binding, or use dry binders. The causes and remedies of chipping associated with machine (dies, punches and pill press) are viz. Groove of die worn at compression point, barrelled die (centre of the die wider than ends), edge of punch face turned inside/inward, concavity too deep to compress properly. This can be overcome with several remedies like polish to open finish, reverse or replace the die, polish the die to make it cylindrical, polish the punch edges and reduce concavity of punch faces and with use of flat punches.

CRACKING

Small, fine cracks determined on the higher and lower central surface of tablets, or very rarely on the sidewall are referred to as 'Cracks.' It's determined as results of fast enlargement of tablets, especially when deep concave punches are used. The Causes and Remedies of Cracking associated with Formulation (Granulation) respectively large size of granules, too dry granules, tablets expands and granulation too cold. It can be solved with remedies like reduce granule size and add fines, moisten the granules correctly and add proper quantity of binder, improve granulation followed with addition of dry binders, compress at room temperature. The Causes and remedies of cracking associated with machine (dies, punches and tablet press) can be respectively given as pill expands on ejection because of air defence; deep concavities cause cracking while removing tablets. The remedies for cracking are the use tapered die, use special take-off.

STICKING

'Sticking' refers to the pill material adhering to the die wall. Filming may be a slow sort of protruding and is basically because of excess wetness within the granulation. The potential reason behind sticking is improperly dried or improperly lubricated granules. The causes and remedies of protruding associated with formulation (granulation) are respectively summarized as granules not dried properly, too little or improper lubrication, too much binder, hygroscopic granular material, oily or waxy materials, too soft or weak granules etc. It can be overcome with remedies dry the granules properly, make moisture analysis to determine limit, increase or change lubricant, scale back the number of binder or use a unique sort of binder, modify granulation and compress under controlled humidity, modify mixing process and add an absorbent, optimize the number of binder and granulation technique etc. The causes and remedies of protruding associated with machine (dies, punches and pill press) are respectively given as concavity too deep for granulation, too little pressure, compressing too fast. It can be resolved with remedies reduce concavity to optimum, increase pressure, reduce speed etc.

PICKING

'Picking' is that the term used once a little quantity of fabric from a pill is projecting to and being removed far from the tablet-surface by a punch face. The problem is additional current on the higher punch faces than on the lower ones. The problem worsens, if tablets are repeatedly manufactured in this station of tooling because of the more and more material getting added to the already stuck material on the punch face. The picking is of explicit concern once punch tips have engraving or embossing letters, as well as the granular material is improperly dried. The Causes and Remedies of picking associated with Formulation (Granulation) are as follows excessive moisture in granules, too little or improper lubrication, low freezing point substances, may soften from the heat of compression and lead to picking, low melting point medicament in high concentration, too warm granules when compressing, too much amount of binder etc. It can be overcome with remedies like dry properly the granules, determine optimum limit, increase lubrication; use mixture oxide as a 'polishing agent', so that material does not cling to punch faces, add high melting-point materials. Use high melting point lubricants, refrigerate granules and the entire tablet press, compress at room temperature, cool sufficiently before compression, scale back the number of binder, change the type or use dry binders etc. The causes and remedies of picking associated with machine (dies, punches and tablet

press) are rough or scratched punch faces, bevels or dividing lines too deep, pressure applied isn't enough; too soft tablets and remedies like polish faces to high lustre, design lettering as large as possible, plate the punch faces with metallic element to provide a swish and non-adherent face, reduce depths and sharpness, increase pressure to optimum etc.

BINDING

'Binding' within the die, is that the term used once the tablets adhere, seize or tear within the die. A film is created within the die and ejection of pill is hindered. With excessive binding, the pill sides are cracked and it's going to crumble apart. Binding is typically thanks to excessive quantity of wetness in granules, lack of lubrication and/or use of worn dies. The causes and remedies of binding associated with formulation (granulation) are too damp granules and extrudes around lower punch, insufficient or improper lubricant, too coarse granules, too exhausting granules for the lubricating substance to be effective, granular material terribly abrasive and cutting into dies, granular material too warm, sticks to the die and dry the granules properly, increase the amount of lubricant or use a more effective lubricant, scale back granular size, add additional fines, and increase the quantity of lubricant, modify granulation, if coarse granules, reduce its size, use wear-resistant dies, reduce temperature, increase clearance if it is extruding respectively. The causes and remedies of binding associated with machine (dies, punches and tablet press) are poorly finished dies, rough dies due to abrasion, undersized dies, too little clearance, too much pressure in the tablet press and polish the dies properly, investigate different steels or different materials or modify granulation, rework to proper size, increase clearance, reduce pressure respectively.

MOTTLING

'Mottling' is that the term won't to describe associate unequal distribution of colour on a pill, with light-weight or dark spots standing get into associate otherwise uniform surface. One reason for marking is also a coloured drug, whose colour differs from the colour of excipients used for granulation of a tablet. The causes and remedies of mottling are a coloured drug used beside colourless or white-coloured excipients; a dye migrates to the surface of granulation whereas drying, improperly mixed dye, especially during 'Direct Compression', improper mixing of a coloured binder solution and use appropriate colorants, amendment the solvent system, Change the binder, Reduce drying temperature with Use a smaller particle size, combine properly and scale back size if it's of a bigger size to stop segregation, incorporate dry colour additive throughout powder mixing step, then add fine pulverised adhesives like tree and gum and blend well and at last add granulating liquid respectively.

DOUBLE IMPRESSION

'Double Impression' involves solely those punches that have a symbol or alternative engraving on them. At the instant of compression, the pill receives the imprint of the punch. Now, on some machines, the lower punch freely drops and travels uncontrolled for a short distance before riding up the ejection cam to push the tablet out of the die, currently throughout this free travel, the punch rotates and at this point, the punch may make a new impression on the bottom of the tablet, resulting in 'Double Impression'. It occurs due to the free rotation of either upper punch or lower punch throughout ejection of a pill. This can be resolved with remedies like use keying in tooling, i.e. insert a key aboard of the punch, so that it fits the punch and prevents punch rotation, newer presses have anti-turning devices, which prevent punch rotation.

The tablet weights area unit chiefly plagued by following reasons:

1. Product variation:

This type of variation is thanks to inconsistent powder density and particle size distribution. Density will amendment on the press, often because of overfilling of the die and re-circulation of the powder on the tablet press, whereas particle size distribution may change when the product becomes unblended throughout transfer or attributable to electricity. This may also change because the product cannot withstand the handling and the mechanical stress it undergoes before it reaching the tablet press.

2. Machine condition:

The problems caused by a pill press that's poorly ready or operated area unit legion. The up and down motion beneath load on a brand new die table ought to be among zero.003 inch of the setting. Care must be taken to ensure that the pressure rolls and cams are in very good condition.

3. Tooling condition:

The punch operating length ought to be taken in thought. Working length is a crucial considers however punches have an effect on pill weight. New tools area unit created to a tolerance of simple fraction of an in., the length of every punch is correct and identical.

4. Powder flow and feed-rates:

Various defects area unit associated with powder flow and feed-rates stem, therefore powder flow and feed-rates should be taken in account while manufacturing of tablets.

3. Coating Equipment

A modern tablet coating system combines several components:

- a. A coating pan
- b. A spraying system
- c. An air handling unit
- d. A dust collector

Significance of Tablet Coating:

1. Tablets coating mask the style, odour, or colour of the drug.
2. Tablets coating management the discharge of the drug from the pill.
3. It provides physical and chemical protection and protects the drug from the stomach surroundings of the abdomen (acid resistant enteric coating).
4. Incorporate of another drug or formula adjuvant within the coating to avoid chemical incompatibilities or to supply serial drug unleash, improvement of pharmaceutical elegance by use of special colours and different printing also can be obtained from pill coating.

4. TRADITIONAL COATING TECHNIQUES:-

Generally three methods are used for tablet coating ^[10-17]

A. SUGAR COATING

B. FILM COATING

C. ENTERIC COATING

A. SUGAR COATING:-

Sugar coating process involves five separate operations viz. sealing/water proofing: provides a moisture barrier and harden the tablet surface, sub coating causes a rapid build-up the tablet size and to round off the tablet edges, grossing/Smoothing: smoothers out the sub coated surface and increases the tablet size to predetermine dimension., colouring gives the tablet its colour and finished size, polishing produces the characteristics gloss etc. The characteristic of sugar coating are given in following table no.1

Table No. 1:- Characteristic of Sugar Coating

| Type | CHARACTERISTIC | SUGAR COATING |
|---------|---|---|
| Tablet | Appearance | Rounded with high degree of polish |
| | Weight increase because of coating Material | 30-50% |
| | Logo or 'break lines' | Not possible |
| Process | Operator training required | Considerable |
| | Adaptability to GMP | Difficulty may arise |
| | Process stages | Multistage process |
| | Functional coatings | Not usually possible apart from enteric coating |

**Fig.2 Steps Involved in Sugar Coating****B.FILM COATING:-**

If the following questions are answered concomitantly then one can go for film coating i.e. Is it necessary to mask objectionable taste, colour and odour? Is it necessary to control drug release? What tablets size, shape, or colour constrains must be placed on the developmental work?

Several ideal requirements of film coating materials can be summarized as solubility in solvent of choice for coating preparation, solubility requirement for the intended use e.g. free water-solubility, slow water solubility or pH scale -dependent solubility, capacity to produce an elegant looking product, high stability against heat, light, moisture, air and the substrate being coated, no inherent colour, taste or odour, high compatibility with other coating solution additives, nontoxic with no pharmacological activity, high resistance to cracking, film former should not give bridging or filling of the debussed tablet, compatible to printing procedure etc.

There are various materials used in film coating as shown in table no. 2. And Table no. 3 summarizes the characteristics of film coating.

Table No. 2: Materials Used in Film Coating

| S. No. | Material | Type | Uses | Examples |
|--------|--------------------|----------------------------|--|--|
| 1 | Film Former | Enteric Non-Enteric | To control the release of drug | Hydroxy Propyl Methyl Cellulose (HPMC), Methyl Hydroxy Ethyl Cellulose (MHEC) |
| 2 | Solvents | ----- | To dissolve or disperse the polymers | IPA and Methylene chloride |
| 3 | Plasticizer | Internal Plasticizing | It Pertains to the chemical modification of the basic polymer that alters the physical properties of the polymer. | Glycerol, Propylene glycol, PEG 200- 6000 Grades |
| | | External Plasticizing | It incorporated with the primary polymeric film former, changes the flexibility, tensile strength, or adhesion properties of the resulting film. | Diethyl phthalate (DEP), Dibutyl phthalate (DBP) Tributyl citrate (TBC) |
| 4 | Colourants | Inorganic materials | For light shade: concentration of less than 0.01% may be used | Iron Oxides |
| | | Natural coloring materials | For dark shade: concentration of more than 2.0% may be required. | Anthocyanins, Caramel, Carotenoids, |
| 5 | Opacuant-Extenders | ----- | Formulations to provide more pastel colors and increase film coverage | Titanium dioxide, silicate (talc & aluminum silicates), carbonates(magnesium carbonates) |

Table No. 3:- Characteristic of Film Coating

| Type | Characteristic | Film Coating |
|----------------|---|---|
| Tablet | Appearance | Retain contour of original core. Usually not as shiny as sugar coat type |
| | Weight increase because of coating material | 2-3% |
| | Logo or 'break lines' | Possible |
| Process | Operator training required | Process tends itself to automation and easy training of operator |
| | Adaptability to GMP | High |
| | Process stages | Usually single stage |
| | Functional coatings | Easily adaptable for controlled release |

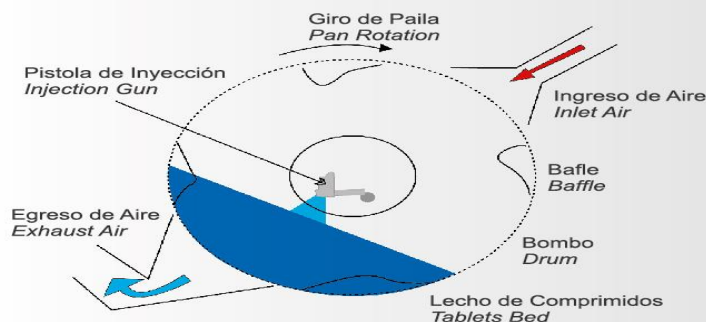


Fig.3 Schematic of film coating process

C. ENTERIC COATING:-

Enteric coating materials have some ideal properties like resistance to gastric fluids, susceptible/permeable to intestinal fluid, compatibility with most coating solution components and the drug substrate, formation of continuous film, nontoxic, cheap and ease of application, ability to be readily printed etc. Some examples of polymers used for enteric coating are cellulose acetate phthalate (CAP), acrylate polymers, hydroxy propyl methyl cellulose phthalate and polyvinyl acetate phthalate etc.

5. TABLET COATING DEFECTS

An ideal tablet should be free from any disablement or purposeful defect. The advancements and innovations in tablet manufacture haven't cut the issues, often encountered in the production, instead have increased the problems, mainly because of the complexities of tablet presses; and/or the greater demands of quality. Majority of visual defects are due to inadequate fines, inadequate wet within the granules prepared for compression, thanks to faulty machine setting. Functional defects are due to faulty formulation. Solving several of the producing issues needs associate in depth information of granulation process and pill presses, and is acquired only through an exhaustive study and a rich experience. Here, we will discuss the imperfections found in tablets along-with their causes and related remedies (see table no. 4). Several tablets are being shown in figure no. 4. The imperfections are a unit legendary as: 'VISUAL DEFECTS' and that they are unit either associated with imperfections in anyone or additional of the subsequent factors:



Figure No. 4: Pictorial Representation of Tablet Defects

6. PROBLEMS AND REMEDIES FOR TABLET COATING ^[18-24]

1. BLISTERING:

It is local detachment of film from the substrate forming blister.

Reason: Entrapment of gases in or underneath the film due to overheating either during spraying or at the end of the coating run.

The cause and remedy of blistering:

Cause

Effect of temperature on the strength, elasticity and adhesion of the film.

Remedy

Use mild drying condition.

2. CRATERING:

It is defect of film coating whereby volcanic-like craters appears exposing the tablet surface.

Reason:

The coating solution penetrates the surface of the tablet, often at the crown where the surface is more porous, causing localized disintegration of the core and disruption of the coating.

The causes and remedies of cratering:

Causes

- I. Inefficient drying.
- II. Higher rate of application of coating solution.

Remedies

- I. Use efficient and optimum drying conditions.
- II. Increase viscosity of coating solution to decrease spray application rate.

3. PICKING

It is defect where isolated areas of film are pulled away from the surface when the tablet sticks together and then part.

Reason:

Conditions similar to cratering that produces an overly wet tablet bed where adjacent tablets can stick together and then break apart.

The causes and remedies of picking

Cause

- I. Inefficient drying.
- II. Higher rate of application of coating solution.

Remedy

- I. Use optimum and efficient drying conditions or increase the inlet air temperature.
- II. Decrease the rate of application of coating solution by increasing viscosity of coating solution.

4. PITTING

It is defect whereby pits occur in the surface of a tablet core without any visible disruption of the film coating.

Reason:

Temperature of the tablet core is greater than the melting point of the materials used in the tablet formulation.

The cause and remedy of pitting

Cause

Inappropriate drying (inlet air) temperature.

Remedy

Dispensing with preheating procedures at the initiation of coating and modifying the drying (inlet air) temperature such that the temperature of the tablet core is not greater than the melting point of the batch of additives used.

5. BLOOMING

It is defect where coating becomes dull immediately or after prolonged storage at high temperatures.

Reason:

It is due to collection on the surface of low molecular weight ingredients included in the coating formulation. In most circumstances the ingredient will be plasticizer.

The cause and remedy of blooming

Cause

High concentration and low molecular weight of plasticizer.

Remedy

Decrease plasticizer concentration and increase molecular weight of plasticizer.

6. BLUSHING

It is defect best described as whitish specks or haziness in the film

Reason: It is thought to be due to precipitated polymer exacerbated by the use of high coating temperature at or above the thermal gelation temperature of the polymers. The causes and remedies of blushing

Causes

- I. High coating temperature.
- II. Use of sorbitol in formulation which causes largest fall in the thermal gelation temperature of the Hydroxy Propyl Cellulose, Hydroxy Propyl Methyl Cellulose, Methyl Cellulose and Cellulose ethers.

Remedies

- I. Decrease the drying air temperature.
- II. Avoid use of sorbitol with Hydroxy Propyl Cellulose, Hydroxy Propyl Methyl Cellulose, Methyl Cellulose and Cellulose ethers.

7. Color variation

A defect which involves variation in colour of the film.

Reason:

Alteration of the frequency and duration of appearance of tablets in the spray zone or the size/shape of the spray zone.

The cause and remedy of color variation

Cause

Improper mixing, uneven spray pattern, insufficient coating, migration of soluble dyes-plasticizers and other additives during drying.

Remedy

Go for geometric mixing, reformulation with different plasticizers and additives or use mild drying conditions.

8. INFILLING

It is defect that renders the intagliations indistinctness.

Reason:

Inability of foam, formed by air spraying of a polymer solution, to break. The foam droplets on the surface of the tablet breakdown readily due to attrition but the intagliations form a protected area allowing the foam to accumulate and 'set'. Once the foam has accumulated to a level approaching the outer contour of the tablet surface, normal attrition can occur allowing the structure to be covered with a continuous film.

The cause and remedy of infilling

Cause

Bubble or foam formation because of air spraying of a polymer solution.

Remedy

Add alcohol or use spray nozzle capable of finer atomization.

9. ORANGE PEEL/ROUGHNESS

It is surface defect resulting in the film being rough and nonglossy. Appearance is similar to that of an orange. Reason: Inadequate spreading of the coating solution before drying.

The causes and remedies of orange peel/roughness:

Causes

- I. Rapid Drying
- II. High solution viscosity

Remedies

- I. Use mild drying conditions.
- II. Use additional solvents to decrease viscosity of solution.
- III. Cracking/Splitting

It is defect in which the film either cracks across the crown of the tablet (cracking) or splits around the edges of the tablet (Splitting).

Reason:

Internal stress in the film exceeds tensile strength of the film.⁴

The Cause of Cracking/Splitting

Cause

- I. Use of higher molecular weight polymers or polymeric blends.
- II. Use lower molecular weight polymers or polymeric blends. Also adjust plasticizer type and concentration.

10. BRIDGING

This occurs when the coating fills in the lettering or logo on the tablet and is typically caused by improper application of the solution, poor design of the tablet embossing, high coating viscosity, high percentage of solids in the solution, or improper atomization pressure. During drying, the film may shrink and pull away from the sharp corners of an 'intagliations' or bisects, results into a 'bridging' of the surface. This defect can be so severe that the monogram or bisect is completely obscured.

Remedy:

Increasing the plasticizer content or changing the plasticizer can decrease the incidence of bridging.

Table No. 4: Tablet Coating Defects with Reason and Their Remedies ^[25-35]

| S.No. | Tablet defects | Definition | Reason | Remedies |
|-------|----------------|---|--|---|
| 1. | Blistering | It is local detachment of film from the substrate forming blister. | Entrapment of gases in the film due to overheating either during spraying or at the end of the coating run. | Milder drying conditions are warranted in this case. |
| 2. | Chipping | It is defect where the film becomes chipped and dented, usually at the edges of the tablet. | Decrease in fluidizing air or speed of rotation of the drum in pan coating | Be careful not to over-dry the tablets in the preheating stage. That can make the tablets brittle and promote capping. |
| 3. | Picking | It is defect where isolated areas of film are pulled away from the surface when the tablet sticks together and then part. | Conditions similar to cratering that produces an overly wet tablet bed where adjacent tablet scan stick together and then break apart. | A reduction in the liquid application rate or increase in the drying air temperature and air volume usually solves this problem. Excessive tackiness may be an indication of a poor formulation. |
| 4. | Twinning | This is the term for two tablets that stick together | Common problem with capsule shaped tablets. | Assuming you don't wish to change the tablet shape, you can solve this problem by balancing the pan speed and spray rate. Try reducing the spray rate or increasing the pan speed. In some cases, it is necessary to modify the design of the tooling by very slightly changing the radius. The change is almost impossible to see, but it prevents the twinning problem. |
| 5. | Pitting | It is defect whereby pits occur in the surface of a tablet core without any visible disruption of the film coating. | Temperature of the tablet core is greater than the melting point of the materials used in the tablet formulation. | Control the temperature of tablet core during the formulation |
| 6. | Cratering | It is defect of film coating whereby | The coating solution penetrates the surface of the tablet, often at | |

| | | | | |
|-----|------------------------|---|---|---|
| | | volcanic-like craters appears exposing the tablet surface. | the crown where the surface is more porous, causing localized disintegration of the core and disruption of the coating. | ----- |
| 7. | Blooming | It is defect where coating becomes dull immediately or after prolonged storage at high temperatures. | It is due to collection on the surface of low molecular weight ingredients included in the coating formulation. In most circumstances the Ingredient will be plasticizer. | ----- |
| 8. | Blushing | It is defect best described as whitish specks or haziness in the film. | It is thought to be due to precipitated polymer exacerbated by the use of high coating temperature at or above the thermal gelation temperature of the polymers. | ----- |
| 9. | Color variation | A defect which involves variation in color of the film. | Alteration of the frequency and duration of appearance of tablets in the spray zone or the size/shape of the spray zone. | A reformulation with different plasticizers and additives is the best way to solve film instabilities caused by the ingredients |
| 10. | Cracking or Splitting | It is defect in which the film either cracks across the crown of the tablet (cracking) or splits around the edges of the tablet (Splitting) | Internal stress in the film exceeds tensile strength of the film. | tensile strength of the film can be increased by Using higher molecular weight polymers or polymer blends |
| 11. | Infilling | It is defect that renders the intagliations indistinctness. | Inability of foam, formed by air spraying of a polymer solution, to break. The foam droplets on the surface of the tablet breakdown readily due to attrition but the intagliations form a protected area allowing the foam to accumulate and “set”. Once the foam has accumulated to a level approaching the outer contour of the tablet surface, normal attrition can occur allowing the structure to be covered with a continuous film. | Judicious monitoring of the fluid application rate and thorough mixing of the tablets in the pan can prevent filling. |
| 12. | Orange peel/ Roughness | It is surface defect resulting in the film being rough and non-glossy. Appearance is similar to that of an orange. | Inadequate spreading of the coating solution before drying. | Thinning the solution with additional solvent may correct this problem. Moving the nozzle closer to the tablet bed and reducing the degree of atomization can decrease the roughness due to “spray drying”. |

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|-----|----------|---|--|--|
| 13. | Mottling | Mottling is uneven distribution of the color on the surface of the tablet, with dark and light patches on it. | It is mainly due to different coloration of the excipient or the degradation product of the tablet is colored. | Coating solution prepare properly in sufficient quantity |
|-----|----------|---|--|--|

6. CONCLUSION

Tablets are the most common and frequently used among oral dosage forms. This is due to its relative low cost and ease of administration. They are the conventional dosage forms compared to any other oral dosage forms. It is necessary for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form with a good bioavailability. Defects in the tablets can arise during manufacturing processes, storage or transport. These visual defects can reduce the acceptability by the users and effectiveness of the product. In this review processing problems in tableting, types of coating, defects, causes and measures to overcome these defects have been discussed and that the same could be minimized and prevented. The focus of this discussion was to establish ways to resolve common defects at the tablet press, coating technology and to identify the root cause of each and finally resolve the defect associated with manufacturing and coating technology.

7. Acknowledgements

The author would like to thank all his mentors and our Principal, Dr. V. V. P. Foundation's College of Pharmacy, Ahmednagar. The notes compiled here are collected over a period of time and may have been reproduced verbatim. Apologize to all researchers if in-advertently failed to acknowledge them in the references.

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