

A Review of Manufacturing Defects in Tablets

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Abstract:

Every unit activity upstream as well as the tablet press can produce defective tablets. Poor quality or non-conforming raw materials could result in exorbitant fines and a wide range of problems. If the material does not compress well or if the processing step described in the formulation does not result in a powder with good flow, compressibility, and ejection qualities, the formulation may be the source of faults. Powder processing and granulation are frequently the cause of defects.

Even the same product run on a different day will respond differently on a tablet press. Changes in the qualities of the raw materials—active ingredients and excipients—from batch to batch are frequently the cause of the fluctuation. to group. Consequently, minimizing these modifications is the objective. Operators of tablet presses, however, have no influence on granulation or formulation. Tablet standards are strict, and there is a large list of potential defects, including variations in weight, stickiness, picking, capping, lamination, and hardness. These variances are the subject of this article. It identifies potential causes of these defects and provides suggestions for preventing and resolving the issues at hand.

Keywords —capping, mixing, granules, punches, compression, cracking

INTRODUCTION

Any cosmetic or functional defects should not exist in a perfect tablet. The improvements and advances in tablet manufacturing have not reduced the production issues that are frequently encountered, but rather have worsened them due to the complexity of tablet presses and/or higher standards for quality.

Throughout production, an industrial pharmacist typically runs across a number of issues. The majority of aesthetic defects are caused by either insufficient fines or moisture in the granules that are ready for compression, or by improper machine settings. Ineffective formulation is the cause of functional problems.

Many production issues may only be resolved by having a thorough understanding of tablet presses and granulation processes, which can only be

attained via extensive study and extensive experience.

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The defects in the tableting process

- i) Capping: Air trapped in the granular material causes a partial or complete separation of the top or bottom of the tablet.
- ii) Lamination: This occurs when air is trapped in the granular substance, causing the tablet to separate into two or more layers.
- iii) Cracking: This occurs when deep concave punches are employed and the tablets expand quickly.

Defects involving Excipient

- iv) Chipping: Very dry granules are to blame.
- v) Sticking: This is the granulation material's adhesion to the die wall.
- vi) Picking: This is the process of removing material from a tablet's surface and preventing it from sticking to the punch's face.
- vii) Binding: These issues (v, vi, vii) are caused by moist or more binder-filled granules.

The flaw had multiple contributing factors.

(viii) Mottling Any one or more of the following causes it: Due to filth in the granular material or on punch faces; oil spots from using oily lubricant; a colored medication that is different in color from the rest of the granular material (excipient-related); inappropriate granular material mixing (process-related).

The issue with Machine

ix) Double Impression is brought on by the punches' free rotation while having some engraving on the punch faces.

Also, each issue is discussed in this part along with its causes and solutions, which may be connected to either formulation (granulation) or machinery (dies, punches, and the full tablet press).

CAPPING

When the upper or lower segment of a tablet separates horizontally, either totally or partially, from the main body of a tablet and comes off as a

cap, either during ejection from the tablet press or during later handling, the phenomenon is known as capping.

Reason: As a tablet is ejected from a die, air that was trapped in the compact during compression expands, which causes capping.

The Reasons for Capping and Its Treatments in Relation to "Formulation"

Causes

- I. There are many fine particles in the granulation
- II. Very low moisture content or too much of a dry state (preventing appropriate binding action).
- III. Granules that haven't dried all the way.
- IV. Use of the wrong or insufficient amount of binder.
- V. An inadequate or inappropriate lubricant
- VI. A chilly granular mass

Remedies

- I. Pass fines through a 100 to 200 mesh screen to remove some or all of them.
 - II. Properly moisten the grains. Add a hygroscopic material, such as PEG4000, sorbitol, or methylcellulose.
 - III. Thoroughly dry the granules.
 - IV. Raising the binder content.
 - V. Including a dry binder, such as powdered sugar, pre-gelatinized starch, gum acacia, powdered sorbitol, PVP, or hydrophilic silica.
 - VI. Increase the lubricant's volume or switch the lubricant's composition.
- At room temperature, compress.
The Root Causes and Solutions for Machine-Related Capping

Causes

- I. Badly made deaths
- II. Punches with beveled edges or deep concave faces.
- III. During ejection, the lower punch stays below the face of the die.
- IV. An improperly adjusted sweep-off blade
- V. Rapid turret movement

Remedies

- I. Polish passes away legally. Look into different steels or materials.
- II. Employ flat punches,
- III. Set the lower punch correctly during ejection.
- IV. Correctly adjust the sweep-off blade to enable proper ejection.
- V. Slow down the turret

A tablet is "laminated" when it is divided into two or more visually distinct horizontal layers. Air being trapped during compression and released after ejection is the cause.

The situation is made worse by the turret's increased speed.

The Roots of Lamination and Treatments Relating to Formulation

Causes

1. Granulated materials that are oily or waxy.
2. An excessive amount of hydrophobic lubricant Magnesium stearate, third.

Remedies

- I. Change the mixing procedure. Include an absorbent or adsorbent.
- II. Reduce the amount of lubricant used or switch to a different kind.

The Causes And Treatments For Lamination In Connection With "Machine"

Causes

- I. Upon ejection from a die, a tablet's periphery rapidly relaxes.
- II. Quick decompression

Remedies

- I. Employ tapered dies, where the upper portion of the die bore has a 3° to 5° outward taper.
- II. Use pre-compression. Lower the ultimate compression pressure and turret speed.

CHIPPING

As a tablet leaves the press or during the handling and coating processes that follow, it is said to have chipped.

Reason: Inadequate machine parameters, particularly incorrect ejection take-off settings.

The Reasons For And Treatments For Formulation-Related Chipping

Causes

- III. Using tape to punch faces
- Too-dry granules, second.
- IV. Too much binding results in bottom chipping.

Remedies

- I. Properly dry the granules or improve lubrication
- II. Wet the granules to cause plasticization. Including hygroscopic materials.
- III. Use dry binders or improve binding.
- IV. The Root Causes And Treatments For Machine-Related Chipping

Causes

- I. Die groove at the site of compression is worn.
- II. Barreled die, second
- III. The punch face's inside or inward-facing edge.
- IV. Concavity that is too deep to adequately compress

Remedies

- I. Replace the die, invert it, or polish the open end.
- II. Rounden the die by polishing it
- III. Smooth down the punch edges
- IV. Make punch faces less concave. use flat punches

CRACKING

Cracks are described as tiny, small fissures found on the top and lower center surfaces of tablets, or extremely infrequently on the walls.

It is seen as a result of the tablets' rapid expansion, especially when deep concave punches are employed.

Formulation-Related Cracking: Causes And Treatments

- I. Granules are a large size.

Causes

- I. Large size of granules.
- II. Too-dry granules, second.
- III. Tablets grow in size.
- IV. Cold granulation

Remedies

- I. Decrease the granule size, Charge fines.
- II. Properly moisten the granules and add the right quantity of binder.
- III. Enhance granulation. Including dry binders.
- IV. At room temperature, compress.

The Root Causes And Treatments For Machine-Related Cracking

Causes

When a tablet is ejected, it swells due to trapped air, and when tablets are removed, deep concavities induce cracking.

Remedies

- Use a tapered die, I.
- II. Employ a unique takeoff.

STICKING

The tablet substance sticking to the die wall is referred to as "sticking."

The main cause of filming, a sluggish sort of sticking, is too much moisture in the granulation.

Granules that have been incorrectly dried or lubricated are the cause.

The Reasons Why Formulation-Related Sticking Occurs And How To Fix It

The Root Causes And Solutions For Formulation-Related Sticking

Causes

- I. Inadequately dried granules.
- II. Insufficient or poor lubrication
- III. Excessive binder
- IV. Granular hygroscopic substance.
- V. Oily or slippery materials
- VI. Weak or too soft granules

Remedies

- I. Thoroughly dry the grains. To establish limitations, conduct a moisture analysis.
- II. Upgrade or modify the lubricant.
- III. Use a different kind of binder or use less of it.
- IV. Adjust granulation and compress while keeping humidity under control.
- V. Change the mixing procedure. Include an absorbent.

VI. Improve the granulation process and binder dosage.

The Root Causes And Solutions For Machine Sticking

Causes

- I. Too deep of a concavity for granulation.
- II. Insufficient pressure
- III. Overcompressing.

Remedies

- I. Optimally reduce concavity.
- II. Apply more pressure.
- III. Slow down

PICKING

The phrase "picking" refers to the act of a small bit of tablet material adhering to and being scraped off by a punch face.

On the higher punch faces rather than the bottom ones, the issue is more common. If tablets are frequently made in this tooling station, the issue gets worse because more and more material is added to the already-stuck material on the punch face.

Reason: When punch tips have engraving or embossing lettering and the granular material is incorrectly cured, picking is especially concerning. The Root Causes and Formulation-Related Treatments For Picking

Causes

- I. Granules with excessive wetness.
- II. Insufficient or poor lubrication
- III. Materials with low melting points may become pickable if the heat of compression causes them to soften.
- IV. A drug with a low melting point and high concentration.
- V. Granules that were too warm to compress.
- VI. Use of the binder is excessive.

Remedies

- I. Dry properly the granules, determine optimum limit.

- II. Increase lubrication; use colloidal silica as a 'polishing agent', so that material does not cling to punch faces.
- III. Add high melting-point materials. Use high melting point lubricants.
- IV. Refrigerate granules and the entire tablet press.
- V. Compress at room temperature. Cool sufficiently before compression.
- VI. Reduce the amount of binder, change the type or use dry binders. The Causes And Remedies Of Picking Related To Machine (Dies, Punches And Tablet Press)

Causes

- I. Punch faces with dings or scratches.
- II. Too-deep bevels or separating lines.
- III. Too soft of tablets; insufficient pressure exerted.

Remedies

- I. High-luster face polishing
- II. Create letters that is as large as you can.
- III. Chromium plate the punch faces to create a smooth, non-adherent face.
- IV. Decrease sharpness and depths.
- V. Optimal pressure should be applied.

BINDING

The word "binding" in the die is used when the tablets stick, lock, or tear in the die. The die develops a coating, preventing the tablet from being ejected. The tablet's sides are fractured and it may crumble apart if there is too much binding.

Binding is typically caused by too much moisture in the granules, a lack of lubrication, and/or the use of old dies.

The Sources And Treatments For Formulation-Related Binding

Causes

- I. Lower punch extrudes around too-wet grains.
- II. An inadequate or bad lubricant
- III. Granules that are too coarse.
- IV. Granules that are too tough to allow the lubricant to work.
- V. Very abrasive granular substance that cuts into dies.

- VI. Too-warm granular substance.
- VII. Sticks to the dice, part

Remedies

- I. Thoroughly dry the grains.
 - II. Use a more potent lubricant or increase the amount you use.
 - III. Lower the granular size, add more fines, and add more lubricant.
 - IV. Change the granulation. smaller granules.
 - V. If the granules are coarse, lower the size. Use wear-resistant dies, VI.
 - VII. Lower the thermostat.
 - VIII. If it is protruding, increase clearance.
- The Root Causes And Treatments For Machine-Related Binding

Causes

- I. Death from a shoddy finish.
- II. Corrosion and abrasion cause rough dies.
- III. A person who is too small passes away. There is not enough space.
- IV. The tablet press's excessive pressure.

Remedies

- I. Correctly polish the dies.
- II. Examine different steels or materials, or alter granulation.
- III. Rework to the correct size. Boost the distance.
- IV. Lower the pressure. Alter the granulation, or.

MOTTLING

The term "mottling" refers to an uneven color distribution on a tablet, with light or dark areas sticking out on an otherwise uniform surface.

Reason: A colored medicine whose color is different from the excipients used in tablet granulation could be one source of mottling

The Roots Of Mottling And Treatments

Causes

- I. A colored medication combined with white or colorless excipients.
- II. As the granulation dries, a dye migrates to the surface.
- III. Incorrect dye mixing, particularly during "Direct Compression."

IV. Incorrect blending of a colored binder solution

Remedies

- I. Apply the proper colorants,
- II. Alter the binder, the solvent system, the drying temperature, and the particle size, as well as
- III. To avoid segregation, properly combine the ingredients and reduce size if necessary.
- IV. At the powder blending stage, incorporate dry color additives, then stir in finely powdered adhesives like acacia and tragacanth before adding granulating liquid.

DOUBLE IMPRESSION

Only punches with a monogram or other engraving qualify for "Double Impression." The tablet acquires the punch's imprint at the time of compression. Now, on some machines, the lower punch freely descends and moves in an uncontrolled manner for a brief distance before riding up the ejection cam to force the tablet out of the die. Now, during this free travel, the punch rotates, and at this point, the punch may make a new impression on the bottom of the tablet, leading to "Double Impression."

Cause

Free rotation of either upper punch or lower punch during ejection of a tablet.

Remedies

- I. Use keying in tooling, i.e. inset a key alongside of the punch, so that it fits the punch and prevents punch rotation.
- II. Newer presses have anti-turning devices, which prevent punch rotation.

Tablet weight: Sources of variation

The tablet weights are mainly affected by following reasons :

Product variation: Inconsistent powder density and particle size distribution may be to blame for this kind of variance. Particle size distribution can change when the product is being transferred or due to static electricity,

whereas density can change on the press due to overfilling the die and recirculating the powder on the tablet press. The product's inability to survive the handling and mechanical stress it experiences prior to arriving at the tablet press may also cause this to change.

Condition of the machine: There are numerous issues that might arise from improper setup or use of a tablet press. A new die table should move up and down under load within 0.003 inches of the setting. The pressure rollers and cams need to be checked carefully to make sure they're in excellent shape.

Tooling condition: The operating length of the punch should be taken into account. Punches have a significant impact on tablet weight depending on the working length. Each punch's length is accurate and consistent, and new tools are manufactured with a tolerance of one thousandth of an inch.

Powder flow and feed-rates: Powder flow and feed-rates should be taken into consideration while making tablets because they are associated to a number of faults.

PROBLEMS AND REMEDIES FOR TABLET COATING BLISTERING

Localized film separation from the substrate that results in blister formation.

Reason: Gas entrapment in or beneath the film as a result of overheating during spraying or at the conclusion of the coating run.
The Cause of Blistering and Treatment

Cause

The strength, elasticity, and adherence of the film are all impacted by temperature.

Remedy

Employ a gentle drying environment.

CRATERING

It is a flaw in the film coating that causes volcanic-looking craters.

reveals the tablet's surface.

Reason: Localized disintegration of the core and disruption of the coating result from the coating solution penetrating the tablet's surface, frequently near the crown where the surface is more porous.

The Roots Of Cratering And Treatments

Causes

- I. Poor drying performance.
- II. A faster rate of coating solution application.

Remedies

- I. Employ the best drying conditions possible.
- II. Increase coating solution viscosity to lower spray application rate.

PICKING

When the tablet sticks together and then separates, there is a flaw where some isolated sections of film are pulled away from the surface.

Reason: Cratering-like conditions that result in an excessively wet tablet bed where adjacent tablets may stay together and eventually separate.

The Roots And Treatments For Picking

Cause

- I. Poor drying performance.
- II. A faster rate of coating solution application.

Remedy

- I. Employ the most effective drying methods available, or raise the inlet air temperature.
- II. Reduce the pace of coating solution application by raising coating solution viscosity.

PITTING

A flaw is when the surface of a tablet's core develops pits without any obvious damage to the film coating.

The temperature of the tablet core is higher than the melting point of the components used to make the tablet, which is the cause.

Pitting's Cause And Treatment

Cause

incorrect temperature of the drying (inlet air).

Remedy

Preheating processes are skipped at the beginning of coating, and the drying (inlet air) temperature is changed so that the tablet core's temperature does not exceed the melting point of the batch of additives employed.

BLOOMING

Coating that gets dull either right away or after extended storage at high temperatures is a fault.

Reason: Low molecular weight components used in the coating formulation have a tendency to accumulate on the surface. The component will often be a plasticizer. 9Blooming: The Cause And Treatment

Cause

Low molecular weight and high concentration of plasticizer.

Remedy

Reduce the concentration of the plasticizer while raising its molecular weight.

BLUSHING

The flaw might be identified in the film as whitish flecks or haziness.

Reason: It is believed that the problem is caused by precipitated polymer that has been made worse by the use of high coating temperatures that are at or above the polymers' thermal gelation temperatures. Blushing's Causes And Treatments

Causes

- I. A hot coating temperature
- II. Sorbitol use in formulation results in a significant decrease in the temperature at which hydroxypropyl methylcellulose, methyl cellulose, and cellulose ethers thermally gel.

Remedies

- I. Lower the air-drying temperature.

II. Sorbitol should not be used with hydroxypropyl methyl cellulose, methyl cellulose, or cellulose ethers.

Colour variation

a flaw that causes variations in the film's color.
Reason: Modification of the spray zone's size or form, as well as its frequency and duration of tablet appearance
The Reasons Behind Color Variance And Solutions

Cause

Poor mixing, an uneven spray pattern, insufficient coating, and the migration of soluble colors, plasticizers, and other additives during drying are all causes.

Remedy

Use gentle drying conditions, geometric mixing, or reformulation with alternative plasticizers and additives.

INFILLING

The intagliations lack distinction due to a flaw.
Reason: The foam that is created when a polymer solution is sprayed into the air is unable to break. The foam droplets on the tablet's surface degrade quickly due to attrition, but the intagliations create a safe zone where the foam can gather and "set." The structure can be covered with a continuous layer once the foam has built up to a level that is close to the tablet's outside shape due to normal wear.
The Origin And Treatment For Filling

Cause

a polymer solution sprayed with air causes the development of bubbles or foam.

Remedy

Use a spray nozzle with a finer atomization setting or add alcohol.

ORANGE PEEL/ROUGHNESS

It is a surface flaw that makes the film gritty and non-glossy. Similar to an orange in appearance.

Reason: Insufficient coating solution spreading before drying.

Causes of Orange Peel and Treatments for Roughness

Causes

High solution viscosity and Quick Drying

Remedies

- I. Make drying conditions gentle.
- II. Add more solvents to the solution to reduce its viscosity.

Cracking/Splitting

It is a flaw when the film either breaks around the tablet's borders or cracks over the tablet's crown.

Reason: The film's internal tension exceeds its tensile strength.

The Reason for Splitting or Cracking

Cause

- I. The use of polymers or polymeric mixtures with a higher molecular weight.
- II. Employ polymeric blends or lower molecular weight polymers. Change the type and concentration of plasticizers as well.

BRIDGING

This happens when the coating completely covers the letters or logo on the tablet and is often brought on by faulty solution application, bad tablet embossing design, excessive coating viscosity, high solids content in the solution, or incorrect atomization pressure.

An intagliation or bisect's sharp corners may be pulled away from by the shrinking and drying layer, causing the surface to "bridge." This flaw might be so serious that

The bisect or monogram is completely hidden.

Solution: Adding more plasticizer or altering the

Bridging can occur less frequently with the use of plasticizer.

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CONCLUSION

Of all the oral dose forms, tablets are the most prevalent and commonly used. This is because it is relatively inexpensive and simple to administer. Tablet defects can develop during production, storage, or transportation.

These aesthetic defects may make the product less effective and less acceptable to users. Defects, their causes, and remedies have all been covered in this review in an effort to reduce and prevent them. The goal of this conversation was to propose strategies for resolving frequent defects at the tablet press, locate each flaw's underlying source, and then fix the flaw before it ever gets there.

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