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Tablet's Common Defects and Solution

Mohammad Rayhan[1*], Mostafa Abu Sadek[2], Mahbubul Hossain[3], Mujammel Hossan[2]

[1]Department of Pharmacy, University of Technology Malaysia, Skudai, Johor, Malaysia
[2]Department of Pharmacy, Manarat International University, Dhaka, Bangladesh
[3]Department of Pharmacy, Southeast University, Dhaka, Bangladesh

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ABSTRACT

Pharmaceutical tablets are one of the most commonly prescribed and consumed forms of medication worldwide. These are compact and easy to administer and it has revolutionized healthcare by providing a convenient and accurate way to deliver essential drugs. However, like any pharmaceutical product, solid tablets can encounter various problems during their manufacturing (granules and machine-related) processes. These issues can range from formulation challenges and quality concerns to patient compliance and dosage accuracy.

Keywords: Tablet, Problems, Solutions, Capping, Sticking, Picking, Manufacturing, Formulation, Challenges

INTRODUCTION

The crucial part of pharmaceutical industry to identify and address these tablet-related problems effectively. By understanding the root causes and implementing viable solutions, manufacturers can ensure the delivery of safe, reliable, and consistent medication to patients [1]. It has been explored some of the most common problems encountered in the production and use of pharmaceutical tablets. It's also delved into innovative solutions and best practices that pharmaceutical companies, healthcare professionals, and patients can adopt to enhance tablet quality, stability, and overall therapeutic outcomes. By gaining insights into these critical areas, we can promote the continued advancement of tablet technology, and ultimately improve global healthcare standards. So, let us embark on this journey to uncover the complexities and solutions surrounding pharmaceutical solid tablets [2].

LITERATURE REVIEW

The tablet capping and solution

In the pharmaceutical industry, a common issue known as "tablet capping" occurs when the top or bottom of a tablet can separate from the main body. Numerous things, including high humidity, too much pressure during compression, and insufficient lubrication, can contribute to this problem [3].

Granulation

- Inadequate lubrication of granules.
- The formulation is too dry or brittle, it may not compress properly.
- The large number of fines in the granules.
- Granular mass too cold to compress firm [4].

Solution

Granulation

- Use 100 to 200 mesh screens to remove some or all fines.
- It's important to moisten the granules. Add a hygroscopic substance. Use Sorbitol, Methylcellulose, or PEG-4000.
- Change the type of lubricant or increase the lubricant dosage.
- Control the room temperature [5].

Machine related problem

- High humidity can cause moisture to penetrate the tablet and weaken the bond between the tablet and its cap.
- Excessive pressure during compression can cause the tablet to crack or break apart.
- High turret speed.

Machine

- Control humidity levels in the manufacturing environment to prevent tablet capping.
- Adjust the compression force to ensure that the tablets are properly formed.
- Reduce turret speed [6].

In conclusion, tablet capping is a common problem in tablet manufacturing, but it can be addressed through careful consideration of the factors that contribute to the issue. By ensuring proper compression force, adjusting the formulation, machine settings, controlling environmental conditions, and improving tablet design, tablet manufacturers can minimize capping and produce high-quality tablets.

Sticking

A tablet defect known as sticking occurs when the tablet surface adheres to the punch face or die wall during compression. Sticking is the adhesion of the material to the faces of the tablet punches or dies following compression, to put it simply. The tablet surface sticks to the lower punch face during sticking, but only a small portion of the tablet surface detaches or develops a pitted surface [7].

Possible reason

- The granulate was not fully dried
- Insufficient lubricant content
- Hygroscopic granular material.
- Use oily or waxy materials.
- Granules are too soft or weak.
- The compression speed TPM (Tablet Per Minutes) too high or too low.

Solutions

- Dry the granules perfectly.
- Use enough and an efficient lubricant
- Add suitable binder
- Modify mixing process and add absorbent
- Granules keep at optimum temperature.
- Adjust the compression turret speed.

Punch related problem

- Punch concavity too deep.
- On the punch surface, emboss letters or a logo.
- Punch tips burred.
- Poorly finish on punch faces [8].

Solution

- Use shallow concave punches or flat which has less concavity.
- Use normal embossing punches or avoid using embossed punches (letters or logos).
- Refinish or replace the punch.
- Polish the refinish punch faces [9].

On the upper and lower surface or on the punch's sidewall, there are tiny, fine cracks.

Binding

Tablet defects known as binding problem occur when a tablet sticks, seizes, tears, or forms a film on the die area that prevents the tablet from being ejected or splits during the molding or pressing process. Punch edges and die punches adhere to by the powder [10].

Granules related problem

- There is an excessive amount of moisture present within the granulate.
- Insufficient quantity of lubricant present in the granulate.
- Excessive binder.
- Granular material is rough and can grind into shapes into dies.
- The granular material is too warm.

Remedy

- Enhance the duration of the granulates drying process.
- It is recommended to utilize an adequate and effective lubricant.
- Use proper amount of binder.
- If the granules are too large, make them smaller and use wear-resistant dies that resist damage.
- The procedure must be conducted in an environment characterized by low humidity levels and reduced temperature.

Chipping

Chipping means the edges of a tablet are breaking off either when it comes out of the machine or when it's being handled

later to coating. Explanation: The machine was not set correctly, particularly the blade that helps remove the item being produced [11,12].

Granules related problem

- The granules are too dry.
- Too much binder.

Solutions

- It is necessary to moisten the granules.
- It is recommended to employ an appropriate binding agent or use dry binders.

Machine related problem

- Lower punch setting too down at tablet take-off blade.
- Poor finish or worn punches and dies.
- Barreled die (The center of die wider than tip straight).
- The Edge of punch face turned inside/inward.

Solutions

- Change the tablet punch.
- Align the lower punch with the die face.
- Polish means to clean, make smooth, or change the die.
- Make the die smooth and round like a cylinder [13].

DISCUSSION

Weight variation

Weight variation is a common problem with tablets that can happen during the manufacturing process. It means that the tablet's weight, either on its own or average weight, may go above or below the limit that is considered acceptable according to guidelines from USP (The United States of Pharmacopoeia), BP (British Pharmacopoeia) and IP (Indian Pharmacopoeia) [14].

Granules related problem

High variation of tablet weight

- There is a large difference in the density of granules.
- There is a big difference in the sizes of granule particles.
- Granules flowability insufficient
- Improper drying.
- The improper amount of glidant [15].

Solution

- Weight differences can be reduced by granulation process and compaction forces during compression.

- To prevent decomposition, it is imperative to take measures to prevent the free fall of the granulate.
- Use additives to make the granulate or powder blend flow better.
- Dry granules properly.
- Use a sufficient amount of glidant.

Machine related problem

- Poor or erratic flow of granules from the hopper.
- Particle segregation as press RPM's increase.
- Particle size not suitable for die diameter.
- Lower punch "hang up" refers to when there is material stuck between the lower punch and the wall of the die or between the lower punch and the punch guide.
- The speed is too fast and the time to fill is too short.

Solution

- Create granules that are all the uniform size. Don't have too much fine powder when directly compressing.
- The particle size in range; Make a maximum ratio of granules by wet granulation.
- Adjust the particle size range to recommended optimum for die diameter
- Make sure there is enough space between die wall and the lower punch; Add more lubricant to the mixture; get rid of fine particles that are smaller than 2 mm mesh.
- Slow down the speed at which the press operates or make the time it takes to fill something longer. [16].

Tablet hardness

The hardness of a tablet can vary and is not always the same. It can fall within a certain range. Hardness variation is a common problem with tablets, where the individual hardness of some tablets may be out of the acceptable range. The limit of how hard a tablet can be determine by testing out a sample tablet, instead of testing different weights [17].

Granules related problem

- Variation in bulk density of the granules.
- Inadequate amount of binding agent.
- Inhomogeneity of granulate particle size.

Solution

- Granules should be more adhesive.
- Use a sufficient and effective binding agent.
- Granules should be more adhesive.

Machine related problem

- The tail over dye is too old or damaged.
- The compression force is too low.
- The eject blade has not fixed properly.

Solution

- Replace or repair tail over dye
- Increase compression force

- Fixed the ejection blade's position [18].

Mottling of tablet

Mottling means that some parts of a tablet have different colors compared to the rest of it. These can be lighter or darker spots that stand out on an otherwise even surface. This kind of tablet problem happens when a tablet is made with a dry coloring agent. Simply put, mottling is when there are dark and light patches on the surface of a tablet [19].

Problem

- Unequal spreading of colored gel solutions causing tablets to form.
- The wrong size of particles either too big or too small affects how colors are spread out.
- The colorants are damp and out of temperature.

Solution

- Need to add unique colorful gel solutions when they are hot, to prevent them from clumping with colder powder mixtures.
- The color solution should be mixed properly to prevent decomposition of colors.
- During the powder blending step, it is recommended to incorporate the dry color additive. Following this, the fine powdered adhesives should be added and mixed thoroughly. Finally, the granulating liquid should be added. To ensure proper drying, it is advised to reduce the drying temperature [20].

Cracking

Cracking is a situation in which small cracks are identified on the top and bottom central surfaces of tablets during the processing of the tablets or during their subsequent use. Hardly are the cracks identified on the sides of the tablets but mainly on the top and bottom surfaces.

Granulation

Problem

- The size of the granulate is excessively large.
- The granulate exhibits excessive dryness.
- Granules are too damp
- Inadequate binder
- Elastic excipients in granules.

Solution

- Reduction the granulate size by a shifter screen.
- The granulate need to either moisturized or dried, and subsequently, a binder should be added.
- Adjust ambient temperature
- Improve granulation, add dry binders
- Exchange or lessen elastic excipients.

Machine related problem

- The tablet undergoes expansion upon ejection as a result of the entrapment of air.
- Cracking of tablets occurs due to the presence of deep concavities during the process.

Solution

- Utilize a die with a tapered shape.
- Decrease punch concavity. Modify the punch concavity to reduce its depth.

Lamination

Lamination, which refers to the separation of layers in a tablet, is a significant issue among various defects. This problem can arise during the storage period or shortly after compression, due to the entrapment of air between the tablet layers or low levels of binding agent. However, this issue can be minimized by enhancing the concentration of lubricant and altering the granulation method. Direct compression technique can also prevent lamination to some extent. It is recommended to always use dry material for feed to avoid this problem [21].

Granulation related problem

- Granules containing oily or waxy substances.
- The amount of hydrophobic lubricant is excessive.

Solution

- The mixing process can be enhanced by incorporating either an adsorbent or an absorbent substance.
- Consider using a reduced quantity of lubricant or opting for an alternative lubricant type.

Machine related problem

- The peripheral regions of a tablet rapidly relax upon ejection from a die.
- Rapid decompression.

Solution

- Use tapered dies, specifically those with an outward taper of 3° to 5° in the upper part of the die bore.
- Use pre-compression step.

Picking problem

Picking refers to the process of removing a small amount of material from a tablet's surface by a punch. This material adheres to the face of the punch, resulting in the term "picking." The issue of picking is more common on the upper punch faces compared to the lower ones. This problem becomes more severe when tablets are repeatedly manufactured using the same tooling station, as more and more material accumulates on the punch face. Picking is especially problematic when punch tips have engraving or embossing letters, and when the granular material is not properly dried [7].

Cause of picking (formulation)

- Inappropriate dried granules.
- Inadequate lubrication.
- The granules are excessively warm during compression.
- Excessive amount of binder
- Hygroscopic excipients.

Solution

- The granules need to adequately dry to maintain optimal moisture levels.
- To enhance the lubrication, increasing the lubricant quantity.
- Sufficiently cool before compression.
- Lessen the amount of binder.
- Control humidity in the compression room.

Cause of picking (machine)

- Rough punch faces.
- Letters such as B, A, O, R, P, Q, and G can be embossed or engraved on punch faces.
- The excessive depth of bevels or dividing lines should be considered.

Solution

- Polish the punch tip.
- To ensure optimal results, it is recommended to refrain from utilizing embossed letters or logos or employing shallow embossing punches.
- Reduce depths and sharpness [20].

CONCLUSION

The challenges faced in the realm of pharmaceutical tablets are diverse and multifaceted, requiring careful consideration and proactive solutions. However, it is essential to recognize that the pharmaceutical industry has demonstrated its resilience and commitment to innovation. With advancements in technology, rigorous quality control measures, and collaborative efforts among stakeholders, significant strides have been made in mitigating tablet-related problems. Pharmaceutical companies have continually sought to improve tablet formulations, optimizing drug delivery mechanisms and enhancing overall therapeutic efficacy. Through research and development, have found innovative ways to address solubility, bioavailability, and stability challenges, ensuring that patients receive safe and effective medications. Furthermore, proper storage and handling procedures, along with strict adherence to good manufacturing practices, have become critical in maintaining tablet integrity from production to patient consumption. By ensuring quality throughout the supply chain, pharmaceutical companies can instill confidence in healthcare professionals and patients alike.

In conclusion, the journey to optimize pharmaceutical tablets is an ongoing process, driven by a shared determination to provide safe, effective, and reliable medications to those who need them most. With a steadfast commitment to quality, innovation, and patient welfare, we can pave the way for a brighter and healthier future in the world of pharmaceutical solid tablets.

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