INTERNATIONAL JOURNAL OF ADVANCE RESEARCH, IDEAS AND INNOVATIONS IN TECHNOLOGY

ISSN: 2454-132X
Impact factor: 6.078
(Volume 6, Issue 3)
Available online at: www.ijariit.com

Design and analysis of pharma tableting radial tools cavity for material optimization- A review

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ABSTRACT

There are lot of reasons for tablet defects whether it comes from upstream or from tablet press. The poor quality of raw materials or not complying with standards, resulting in unnecessary fines leading to a host of defects. The formulation may be a source of defect if the material does not compress well or if the processing phase stated in the formulation fails to produce a good flow of powder; Tablet press operators, however, don't have any control over formulation and granulation. Tablet specifications are tight, and the list of possible defects is long: Variable weight, sticking, picking, capping, lamination, variable hardness, among others. This article focuses on these variations. It pinpoints the possible causes of these defects and offers advice on preventing and fixing the source of the problems. When tablet is free from visual defect or functional defect then we can say that it is an ideal tablet. The advancements and innovations in tablet manufacture have not decreased 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. An 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 faulty formulation. Solving many of the manufacturing problems requires an in–depth knowledge of granulation processing and tablet presses, and is acquired only through an exhaustive study and a rich experience.

Keywords**—** *Punches, Compression, Tablet Tool and Die Design, Tablet Defects*

1. INTRODUCTION

As Per Today's increasing Demand in a pharma as well as medical sector, at the same time cost of medicines increased, some medicines are not affordable for the common man. Few reasons are day to day increasing cost of production, so in this work we are optimizing the cost of production with the help of analysis and optimization of material, which affect in reduction of basic cost of medicines.

Tablets are the most common and widely used in oral dosage types. This is because of the relatively low cost and ease of administration. Tablet defects can occur during manufacturing, storage or transport. Such visual defects will reduce the acceptability of consumers and the efficacy of the product. Defects, causes and steps to resolve these defects have been addressed in this analysis and could be reduced and avoided. The purpose of this discussion was to find ways to resolve common flaws in the tablet press, and to determine the root cause of each flaw, and eventually to resolve the flaw before it enters the tablet press.

2. LITERATURE REVIEW

Dr. Charles Kettler, et.al. [2017][1]

This paper clarified the problems of the tablet sticking and picking that are prevalent in the tablet manufacturing industry, whether medicinal, nutraceutical or confectionery. Sometimes, there is a sense of urgency in the controlled world of drug-product production to develop a new supply of molecules. Nonetheless, this urgency can lead to hasty decisions to enter clinical trials or to apply a formulation for regulatory approval that ultimately results in unanticipated compression scale-up problems. Issues of sticking and picking usually emerge from either formulation or tablet design inadequacies. These arise due to differences in the physical properties of the excipients and dry formulations.

Kevin Queensen, et.al. [2018][2]

Explained Many of the options available for punches and dies to help compact challenging drug products. One of the commonly overlooked punch modifications, the extended head flat, raises the width of the flat area above the punch head. Normally, this alternative does not entail any adjustments to the news. The extended head offers multiple advantages, including a longer time of residence– the period the head flat spends in contact with the pressure roll–at a given press speed for better lightweight, poorly compressible goods. The longer time of residence may even reduce the amount of force required to achieve the particular hardness of the tablet.

Partibhan Anbalagan, et.al. [2017][3]

Developed flat-sided punches with a radius edge configuration were beneficial in tablet production as they allowed for better powder densification, which often increased the mechanical strength of the tablets produced as well as reduced capping patterns. Analysis of lactose and paracetamol-starch tablet mechanical properties revealed that tablets developed using radius edge punches consistently exhibited better mechanical quality than bevel edge punch tablets. The presence of the radial curvature on the edge of the flat-sided punch was able to allow deeper penetration of the die cavity during the compression process Produce enhanced powder consolidation in the die required for interparticle bonding. The curvature may have made it possible for more uniform compression force to spread through the compact, thus the localized stress zones and therefore less compact elastic expansion during decompression. The positive impact of the radius edge architecture on the compaction was also noticeable at the higher turn. The use of pre- compression force and dwell phase extension (by roll displacement) at the pre-compression event improved the compression efficiency of radius edge punches to a greater extent compared to bevel edge punches due to enhanced particle densification under compression by radius punch face nature at the pre-compression level. Overall, the results in this study provided a better understanding of the advantages and disadvantages of edge adjustments on the tablet punch face for tablet properties and could be useful for compression device designs.

Bill Turner, et.al. [2015][4]

The three most common processing routes for the preparation of different powdered components for compression have been identified: direct compression blending, dry granulation and wet granulation. Determination of the path to be used is based on the characteristics of the tablet needed to meet the clinical specifications of the drug.

Direct compression is used if the materials (API, excipient, etc.) can be blended and compressed to meet the requirements for tablet dissolution and material quality. Direct compression is a simple (and least costly) method for combining the active pharmaceutical ingredient (API) and the excipients, fillers and lubricants required to make the desired pill.

Care must be taken to ensure that the consistency of the blend is maintained prior to compression. Granulation is a process for bringing the particles together and forming granules, either by compaction or by the application of a binding agent. Dry granulation is used when the materials in the mixture are susceptible to moisture or heat and are not ideal for direct compression mixing. This is a mechanical joining of the particles without the use of a solvent to bind them. Particles are normally compacted using a roller compactor or chilsonator in this process. It increases their density and helps in the production of granules from smaller particles. The resulting ribbon or pellets are then milled into the powder with the desired particle size distribution, which is then stored.

As well as the time-consuming procedure, it is sometimes important to comply with the product performance requirements. Wet granulation can cause problems during tablet compression if latent moisture is retained in the finished powder. Coating, laminating, sticking and picking are common issues that may need to be discussed and resolved before manufacturing. Many tablet compression devices are found. The compression tooling of the tablet should be designed and manufactured with respect for the product being compressed. There is often too much focus on the use of a company standard tablet setup, even though each formulation is unique. Ideally, tablet designs and compression methods for each individual product and formulation should be optimized. Today, with many utilitarian manufacturers.

Standard tool steels are regularly selected for their overall balanced properties and for their ability to handle shock loading conditions. Many steels are only suitable for punching, while others are only suitable for dies. For example, due to its high chromium content and high carbon content, D3 steel exhibits high wear resistance but is very low when it absorbs impact loads and compression stress. It is therefore a good medium for dies, but a poor choice for punches. Higher chromium content steels are perfect in situations where the substance being compressed is corrosive or sticky, whereas higher Rockwell hardness tool steels are ideal in situations where abrasive wear is a primary concern. Tooling solutions such as shortened, reinforced lower tips and undercut dies are available.

Dale Natoli, et.al. [2011][5]

Predicted the most common problem encountered in tablet manufacture would have to be granulation adhering to the tool face, commonly known as 'sticking'. Tablet manufacturers often have to struggle through compressing a batch of sticky product, and sometimes – due to the severity of the sticking – are unable to compress any tablets at all. Typically, sticking is unnoticed or unrecognized during product development and so will often commence and/or worsen once the product reaches production when the dynamics of weight, friction, heat, powder flow, segregation and dwell time – to name but a few, come into play. The most important factors for consistent tablet production are tablet press cleanliness and proper maintenance. Improperly set or maintained lower punch retainers is a common cause of variable tablet weight and hardness, whereas improper or inconsistent tool working length would typically be responsible for any deviation in tablet hardness and thickness.

The most important contributor to tableting speed – or indeed to tablet production – has been the acceptance of multi-tip tooling. This has been used for decades in the industrial, food and confection industries, but only in the last 10 years has multi-tip tooling been accepted and used in the pharmaceutical industry on rotary tablet presses. Tablet manufacturers producing micro-tabs are experiencing speeds of over 5,000 tablets per second. The main concern with using multi-tip tooling is the ability to compress consistent-quality tablets and if not then the ability to validate the tablet reject system to ensure that out-of-spec tablets are discharged.

Dale Natoli, et.al. [2006][6]

In this study explained that Punches are engineered and manufactured to consistent lengths. The working length of a punch is the distance from the head flat to the lowest measurable area of the punch cup. See Figure 1. The figure also illustrates the cup depth and the overall length, which is the distance from the head flat to punch tip. The punch tip comprises the cup and the land, as shown in Figure 2.

Uniform tool length is critical for maintaining tablet consistency and smooth press operations. The most important dimension of the punch related to tablet quality is the working length, followed by the cup depth, and then the overall length. To achieve the highest level of tablet uniformity, most reputable manufacturers of tablet compression tooling can provide a punch-length matching report. Setting up the tablet press in the sequence of the supplier's matching report will provide the best scenario for tablet consistency.

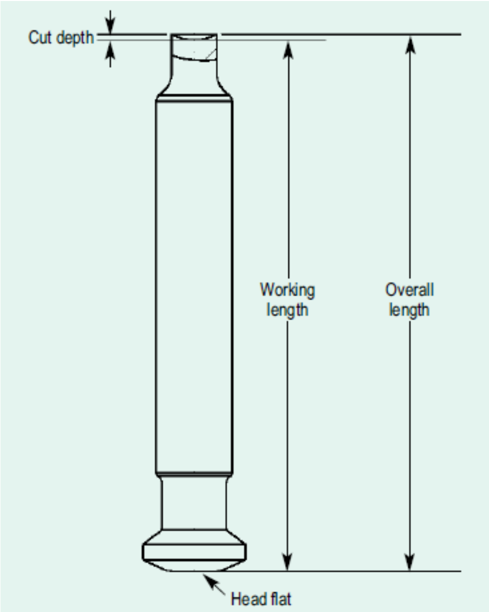

Fig. 1: Cup depth, working length, overall length, and head flat of a tablet press punch

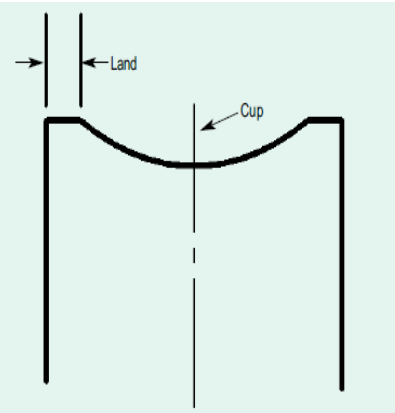

Fig. 2: Land and punch up

Michael D. Tousey, et.al. [2003][7]
In this paper, stated that the most popular problems tablet making Sticking is one of them. This happens when granules are applied to the faces of the punches instead of being fused together to create a uniform disk. The pictures above show examples of tablets that have been rejected due to sticking. Figure 3 shows the surface of the upper punch with the sticking element., you may have to visually inspect the tablets. This certainly will slow production and decrease yields, but there is no alternative. The formulation is completed; you can't send it back down the hallway for reprocessing.

The one inference you can draw from this article is that a sticking or picking problem may have one or more triggers. Polishing the punches during the production process is a temporary fix, not a long-term solution. Environmental factors can influence how well a tablet is shaped. Many materials are so sensitive to temperature and humidity that they can compress differently or not at all with a slight temperature. If you are the trouble shooter in charge of solving a stuck problem, analyze the problem in the press and work upstream from there. Research all process variables and collect as many data as possible. Ultimately, before you make a change, try to make one change at a time.

Fig. 3: Product sticking to the face of an upper punch

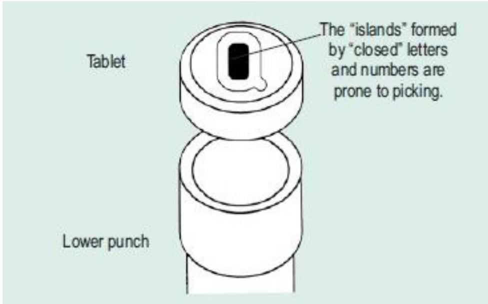

Fig. 4: An example of picking

Abhinav Singh Rana, et.al. [2013][8]
Identified problems in the production of tablets may be due to problems in the formulation or compression equipment, or both. Thus, we can classify the problems in the following types:
Defects related to the tablet phase

(a) Capping: Partial or complete separation of the top or bottom of the tablet due to air- tightness in the granular content.
(b) Lamination: is the division of the tablet into two or more layers due to air trapping in the granular material.
(c) Cracking: is due to the rapid expansion of tablets when deep concave punches are used.
(d) Chipping: This is due to very dry granules.
(e) Sticking: it is the adhesion of the granulation material to the die wall
(f) Picking: it is the removal of the substance from the surface of the tablet and its adhesion to the face of the punch.
(g) Binding: Such issues are due to a higher level of binder in granules or wet granules. Defect attributable to more than one factor
(h) Mottling: either due to one or more of the following factors: due to a colored substance having a color different from the rest of the granular material (Excipient-related); improper mixing of granular material (Process-related); dirt in granular material or on punching faces; oil stains using oily lubricant. The defect is linked.
(i) Double Impression: this is due to the free movement of the punches, which have some engraving on the punch faces. In addition, each problem is defined in this section along with its causes and solutions, which may be linked to either the formulation (granulation) or the system (dies, punches and whole tablet presses).

3. CONCLUSION

From the analysis of all the literature, it is concluding that there is room for modifying or improving the tool & Die design on the basis of some of the problems listed below,

3.1 Corrosion of Tooling

Corrosion of tooling can be a result of the environment in which they are used or a chemical reaction between the granulate and the tooling. [Figure 5]

Fig. 5: Corrosion of Tooling

3.2 Punch Tip Cup Breakage

Punch tip breakage is a catastrophic failure of a punch. This can be due to improper specification, design, material condition or misuse. It is possible that a combination of these factors can act together to cause this problem. [Figure 6]

Fig. 6: Punch Tip Cup Breakage

3.3 Punch Tip Distortion

Punch tip distortion such as bending or ‘splaying out’ of the punch tip edge is usually a result of excessive press force applied in relation to the design and condition of the punch. This is more common on punches with very small punch tips. [Figure 7]

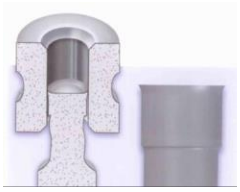

Fig. 7: Punch Tip Distortion

3.4 Tip Wear by abrasion

Tip wear or abrasion is the result of frictional forces applied to the tooling surfaces where the granulate is the abrasive media. This normally appears as a series of scratches or striations to the tool surfaces and some granules are so aggressive, they can remove large areas of the tooling material. The result of this will be poor quality tablets and worn tooling. [Figure 8]

Fig. 8: Tip Wear by abrasion

3.5 Pitting / Impregnation of Tip

Pitting is a deterioration of the punch face caused by impregnation from the granulate being compressed. This can happen faster and more severely when compressing hard or sharp granules such as vitamins and minerals etc. this type of deterioration can lead to other problems such as tablet picking or sticking of the product to punch faces. [Figure 9]

Fig. 9: Pitting/Impregnation of Tip

So, there is scope for researching to improve the life of punch by following aspects:

(a) Design of punch cup based on edge angle, edge thickness and cavity profile for superior strength.
(b) Selection of punch material to avoid tip deformation and cyclic fatigue failure.
(c) To promote appropriate coating of tip to avoid pitting, abrasive wear, corrosion and sticking of granules.

4. REFERENCES

[1] A cover story “Sticky situation?” by Dr. Charles Kettler,in EPMMAGAZINE,May 2017;22- 23.
[2] An Article “Tablet Tooling Tech” by Kevin Queensen, in Scientistlive, 2018-12; 61.
[3] P. Anbalagan et al. / International Journal of Pharmaceutics 524 (2017) 373–381.
[4] A Research Article “Tooling Design – How Tooling Options can Benefit Different Types of Pharmaceutical Formulations During Tablet Compression” by Kevin queensen & Bill Turner, in InternationaL Pharmaceutical Industry, Autumn 2015 Volume 7 Issue 3; 90-94.
[5] A Research Article “Progrssion in tablet compression” by Dale Natoli, in Industrial Pharmacy, December 2011 Issue 32; 4-6
[6] A Research Article “Understanding the importance of punch length & Cup Depth” by Dale Natoli, in Tablets & Capsules, July 2006.
[7] A Research Article “Sticking & Picking: Some causes & Remedies” by Michael D. Tausey, in Tablets & Capsules, October 2003.
[8] Rana et al Journal of Drug Delivery & Therapeutics; 2013, 3(6), 200- 206.

