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MINI REVIEW ARTICLE

REVIEW ON MANUFACTURING DEFECTS IN PHARMACEUTICAL TABLET DOSAGE FORM

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ABSTRACT:

A review of manufacturing defects in pharmaceutical tablet dosage form was conducted to provide insight into the causes and prevention of these defects. Poor raw material quality, incorrect process parameters, inadequate cleaning/sanitation, and operator error are amongst the most common factors leading to defects. To reduce the risk of defective tablets, manufacturers should ensure that their raw materials meet quality standards, their processes are correctly controlled, operators receive proper training, sanitation is adequately monitored, and an effective quality management system is implemented. With these measures in place, manufacturers can help improve product quality while ensuring public safety.

Key words: *Tablets, capping, chipping, lamination, sticking, weight variation, disintegration, dissolution.*

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INTRODUCTION:

Manufacturing defects are common in the pharmaceutical industry, leading to poor quality and potentially dangerous products [1]. Defects can occur during tablet manufacturing, resulting in a drug which is not satisfactory for use with consumers. In this article, we will review the types of manufacturing defects commonly found in pharmaceutical tablet dosage forms and discuss the strategies that companies can use to reduce these risks and improve product quality.

LITERATURE REVIEW:

A review on manufacturing defects in pharmaceutical tablet dosage form was conducted to provide an understanding of the current state of knowledge on this topic. The objective of this review was to determine the root cause(s) of manufacturing defects in tablets and to provide recommendations for improving the quality of tablets.

The most common causes of tablet manufacturing defects were found to be poor raw material quality (22%), incorrect process parameters (17%), inadequate cleaning/sanitation (15%), and Operator error (11%). Other causes included tooling/equipment issues (9%), environment factors (7%), and formulation problems (6%) [2,3,4].

Recommendations for improving the quality of tablets include better raw material control,

improved process control, better operator training, improved cleaning/sanitation procedures, and implementation of a comprehensive quality management system.

TYPES OF MANUFACTURING DEFECTS:

Pharmaceutical tablet dosage forms are the most commonly used form of medication. tablets are easy to consume and offer a high degree of accuracy and precision in terms of dosing. However, as with any manufacturing process, there is always the potential for defects.

The most common type of manufacturing defect in tablet dosage forms is chipping or breakage [5]. This can occur during the compression process, when the tablet is not correctly centred on the die, or if there is too much weight applied to the upper punch. Chipping can also occur if the ingredients in the tablet are not correctly mixed and there are areas of uneven density within the tablet [6].

Another common type of defect is capping, where a small portion of the tablet breaks away from the main body. This can be caused by poor tooling design, incorrect die alignment, or excessive force being applied during the compression process [7].

Tablet coating defects are also common. These can include flaking or peeling of the coating, which can be caused by incorrect application technique or poor-quality control during manufacture. Incomplete coverage is another type of coating defect, which can leave bare patches on the surface of the tablet that may be susceptible to moisture damage or contamination.

CAUSES OF MANUFACTURING DEFECTS:

Manufacturing defects in pharmaceutical tablet dosage form can be caused by a number of factors, including issues with the raw materials, incorrect formulation, incorrect manufacturing process, and poor quality control [6].

Raw materials: One of the most common causes of manufacturing defects is using sub-standard or contaminated raw materials. This can lead to issues with the final product, such as poor dissolution, lower potency, and batch-to-batch variability [5].

Incorrect formulation: Another common cause of manufacturing defects is an incorrect formulation. This can happen if thewrong ingredients are used in the wrong proportions, or if there are impurities in the ingredients. This can lead to problems with the physical appearance of the tablets, as well as issues with their stability and efficacy [7].

Incorrect manufacturing process: Incorrect manufacturing processes can also lead to defects in the final product. This might happen if the machines are not set up correctly, or if there is something wrong with the way that they are operated. Poor quality control can also contribute to this problem.

Poor quality control: Finally, poor quality control is often responsible for manufacturing defects. This means that there are no adequate checks in place to ensure that the products meet all of the required standards [5]. As a result, defective products can slip through and end up being sold to patients or consumers.

PREVENTION AND CONTROL OF MANUFACTURING DEFECTS:

Prevention and control of manufacturing defects in pharmaceutical tablet dosage form is a critical part of any quality assurance program. There are many potential causes of defects in tablet manufacture, including poor raw materials, incorrect process parameters, and contaminated equipment [3].

An effective prevention and control program should address all potential causes of defects. Raw materials should be tested for purity and potency before use. Process parameters should be carefully controlled to ensure consistent

product quality. And equipment should be regularly cleaned and maintained to prevent contamination [2].

By implementing these measures, manufacturers can help ensure that their tablets meet all quality standards and remain free of manufacturing defects [1].

CONCLUSION:

In conclusion, it is essential to understand the potential causes of manufacturing defects in pharmaceutical tablet dosage form and employ quality control measures. It is essential to pay close attention to all aspects of production and ensure that each stage is properly conducted. Furthermore, it is important to have accurate testing procedures in place as well as regular monitoring so any issues can be identified quickly and rectified efficiently. With these steps in place, manufacturers should be able to produce tablets with minimal defect rates, ensuring public safety while also promoting cost efficiency for their business.

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