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A STUDY ON PROCESS DRIFT OF DIRECTLY COMPRESSIBLE MATRIX TABLETS OF ISONIAZID

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ABSTRACT

Solid oral dosage forms are the preferred route for many drugs and are still the most widely used formulations. Of these, tablets offer the lowest cost approach. Matrix tablets serves as an important tool for oral dosage forms. Pharmaceutical industry engaged in making solid dosage form is facing critical problems in proving their process reproducibility. Even that has reduced profits, especially because of critical deviations which are consequences of continuous process and inadequate research. Up-scaling can be challenging as minor changes in parameters can lead to varying quality results. The main objective of the work was to select critical process parameters (CPP) using retrospective data of a developed product and to establish a design of experiments (DoE) that would improve the robustness of the tableting process. Batches were selected based on the quality results generated during batch release, some of which revealed quality deviations concerning the appearance of the coated tablets. The Minitab 17 software was used for data processing to determine critical process parameters in order to propose new working ranges. This study confirms that it is possible to determine the critical process parameters and create design spaces based on retrospective data of production batches. This type of analysis is thus converted into a tool to optimize the robustness of existing processes. This study will help to determine a design space which can be established with minimum investment in experiments.

KEYWORDS: Direct compression, Formulation variables, Process variables, matrix tablets, Isoniazid.

1. INTRODUCTION

A process drift is an unintended, unexplained or unexpected trend of measured process parameter(s) and/or resulting product attribute(s) away from its intended target value in a time- ordered analysis over the lifetime of a process or product. Process drift is the consequence of variation in a variety of process inputs, including raw materials, manufacturing personnel, and machine (man-machine) interactions or processing conditions. When robust systems are not implemented and capable tools are not used to prevent process drift, resulting manufacturing problems may include: low product yield, batch delays, ingredient and packaging variability, batch failures, product quality-related clinical failures, investigations, recalls, product seizures, injunctions, and consent decrees.[1] The use of tools and approaches such as process analytical technologies (PATs), QbD, in vitro–in vivo correlation (IVIVC), and more thorough excipient characterization should improve the robustness of the finished products and minimize or prevent unintended drift in the quality of the affected commercial drug products.[2]

Many studies on the influence of the powder's mechanical characteristics on the performance of the tablet have been performed in the past.[3-14] Optimization technique is an ideal tool for preparing better quality of dosage forms. This technique is widely used for developing optimal dosage forms and a better process of manufacture.[15]

Optimization was considered as an economical and efficient method which helps understand the relationship between independent and dependent variables. Optimization has been gaining popularity in pharmaceutical research, day by day, since the best results can be obtained in a limited number of experiments.[16]

Direct compression involves simple blending of active pharmaceutical ingredient (API) with other ingredients and direct compaction of the resultant mixture. In contrast to direct compression, wet granulation not only increases the cycle time, but also has certain limits imposed by thermolability and moisture sensitivity of the active ingredient. The unnecessary exposure of any