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Review on Scale Up and Process Validation of Lacidipine Tablets

Rahul P Gaikwad[1], Sameer S Sheaikh[2*] and Dinesh Deshmukh[3]

*[*1]Uttamrao Deshmukh Institute of Pharmacy, Balsond-Hingoli, Maharashtra, India*

[2]Durgamata Institute of Pharmacy, Dharmapuri-Parbhani, Maharashtra, India

[3]Uttamrao Deshmukh Institute of Pharmacy, Dharmapuri-Parbhani, Maharashtra, India.

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ABSTRACT

Objective: The objective of this protocol is to define the procedure for process validation and to establish documented evidence that the manufacturing process is in state of control. Review the definition and types of validation. Understand the requirements for documentation and key stages in process validation. It is essential part of GMP. Definition of desirable attributes of the drug product. Determination of the controls or testing parameters that will be measured or tested.

Method: Concurrently 3 batches were taken and all critical parameters evaluated for fixing optimum process parameters for process validation.

Results: The risk assessment was done for each step, and the critical parameters were validated. All the tests was found to be within the limits, and validated. Physicochemical parameter of tablets compressed with granules obtained at final impeller amperage of 11.5 to 12.5 amps, which comply with specification. The parameters in granulation stage are suggested for binder addition time, kneading time and discharge time. In the coating process all the parameters in critical steps were found within the specified limits. The sieve analysis was done for all the three batches. The sieve used and % retains are found to be within the specified limits. In the hopper study, all the parameters were found to be within the specified limits and hence the critical steps were validated. The dissolution studies for all three batches and it complies with the specification.

Conclusion: The manufacturing of three batches of common blend for Lacidipine tablets 6 mg was conducted for a batch size of 94.50 kg (210,000 tablets). The study involved validating the process variables of this transferred product to show that the process is under control. The study includes the validation of critical steps of manufacturing such as blending, drying, granulation, compression and coating. The process validation of Lacidipine tablets showed that there was no significant batch-to-batch variation. Therefore it can be concluded that the process stands validated and the data can be used in regulatory submission for obtaining marketing authorization for the Lacidipine tablets.

Keywords: Process validation, Lacidipine, Parameters, GMP

INTRODUCTION

The basic principle of quality assurance is that a drug should be produced that is fit for its intended use. In order to meet this principle, a good understanding of process and their performance is important. Quality should be built into the manufacturing process. These processes should be controlled in order that the finished product meets all quality specifications [30].

DEFINITION OF VALIDATION

WHO (World Health Organization)

The validation in the same way but elaborates considerably on the concept "Validation studies are essential part of good manufacturing practice and should be conducted in according with predefined protocols [30]. A Written report summarizing results and conclusions should be recorded, prepared and stored. Process and procedures should be established based upon the validation study and undergo periodic revalidation to ensure that they remain capable of

Corresponding author: Sameer S Sheaikh, Durgamata Institute of Pharmacy, Dharmapuri-Parbhani, Maharashtra, India, E-mail: sameersheaikh1980@gmail.com; sameer_sheaikh80@rediffmail.com; durgamataiop@gmail.com

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