Optimization of Direct Compression Aspirin Tablet Using Statistical Mixture Design

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ABSTRACT

The objective of this study was to optimize aspirin tablet by using statistical mixture design based on three tablet excipients: chitin (CT), dibasic calcium phosphate (DCP) and corn starch (CS) and to compare the optimized formulation with the commercial one. The direct compression method was used to prepare the tablets since it is the most efficient process. The appropriate experimental design was a statistical mixture design. Ten formulations from the experimental design were determined for angle of repose, percent compressibility, tablet hardness, percent friability, log disintegration time and drug release profile. All data were analyzed by using statistical programs. Contour plots of each response were depicted, based on the equation given by the statistical-fitted models. With the optimization of more than one criterion, a combined contour plot was made so that the optimum formulation to satisfy the overall goal was obtained. The scale up formulation was selected from the optimized area of the combined properties. The results suggested that the selected formulation had clearly higher hardness and shorter disintegration time than the commercial tablet. The dissolution study showed no significant difference between the optimized formulation and the commercial tablet. It can be concluded that optimization is an effective technique which can be used to obtain the pharmaceutical formulation with the required characteristics.

Key Words: Aspirin, Augmented Simplex Centroid Design, Direct Compression, Mixture Design, Optimization

INTRODUCTION

A pharmaceutical formulation is composed of several composition factors and process variables. These factors and variables not only affect the characteristic property of the dosage form but also make it difficult to formulate. Consequently, expertise and experience are required to design any pharmaceutical formulation. Formulation experience with pharmaceutical preparation generally can guide a formulation expert to select those variables that most likely have an effect on those corresponding responses.

In the development stage of a direct compression tablet, several variables may need to be considered simultaneously to achieve the optimum result. Traditional formulation designs were based on trial and error. It is time-consuming, unreliable, costly and often