Original Article

Prepration And Optimization Of Bilayer Orodispersible Tablets Of Fenoprofen Calcium By Using Quality By Design Approach

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Abstract

Objective: The goal of this work was to prepare and optimize a two-layer orally disintegrating tablet containing fenoprofen calcium using a Quality by Design approach.

Methods: Nine combinations (ODT1 to ODT9) with all promising combinations were created using a 3^2-factorial design with two independent variables: super disintegrant concentration, AC-di-sol (1-3%) (X_1) and Crospovidone (1-3%) (X_2) at three levels of -1, 0 and 1. It was calculated how these two factors would affect two dependent parameters: disintegration time (Y_1) and friability (Y_2). All of the powder mixtures had been tested for precompression parameters. Also, the tablets were manufactured using the technique of direct compression, which was then tested for post-compression parameters. Surface response plots and polynomial equations were used to investigate the influence of a change in the concentration of two specified factors on dependent parameters. The response prediction plot yielded an optimized formula for which compatibility stability was evaluated.

Result: To demonstrate the validity of the evolved mathematical model, an optimized formulation containing 11.333 mg of Crospovidone (0.5) and 15.959 mg of Ac-di-sol (0.5) with a friability of 0.599% and disintegration time of 132 sec. was created. The compatibility of drug and excipients was demonstrated.

Conclusion: Based on the data, it can be concluded that no differences in friability, drug content, disintegration, or in vitro drug release from the optimized formulation were found during stability experiments, confirming the optimized formulation's stability.

Keywords: Fenoprofen Calcium, Quality by design, 3^2 factorial design, Orodispersible Tablets, Direct compression.

INTRODUCTION

As per the European Pharmacopoeia's 10th edition, OroDispersible tablets (ODTs) have a maximum disintegration time of 3 minutes and are easily accepted by patients.[1-3] Tablets that quickly dissolve are becoming more popular as innovative medicine delivery methods.[4-5] One advantage of this pharmaceutical formulation is that water consumption is not necessary during delivery.[6-7]

The term "arthritis" is frequently used to describe any condition that has an impact on the joints. The knees, wrists, fingers, toes, and hips are examples of joints, which are areas of the body where bones meet. These illnesses are