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Original Article

FORMULATION OF LEVOFLOXACIN AS ORODISPERSIBLE TABLETS USING A READY-MADE BLEND OF EXCIPIENTS COMPARED WITH CLASSIC FORMULATION STRATEGIES

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ABSTRACT

Objective: Orodispersible tablets are designed to undergo rapid dispersal when they are placed in the mouth prior to being swallowed. The aim of this study was to compare the performance of a ready-made excipients blend designed for orodispersible tablets with several other conventional methods for the manufacture of tablets using levofloxacin as the active pharmaceutical ingredient.

Methods: Several different formulas were prepared to compare the powder characteristics, and the resulting powders were compressed into tablets using the direct compression method. The result compressed tablets was then evaluated in terms of their physical characteristics and drug release properties.

Results: The results of these experiments showed that the use of ready-made blend provided several advantages over the conventional methods in terms of physical properties of the powders and tablets, as well as their drug release and dissolution properties.

Conclusion: The use of a ready-made powder blend in formulation of ODT of model drug levofloxacin had an advantage over the classic methods of formulation.

Keywords: Orodispersible tablets, Levofloxacin, Prosolv ODT.

INTRODUCTION

Orodispersible tablets (ODTs) are defined as tablets that disperse or disintegrate in less than 1 minute in the mouth prior to being swallowed, which results in the rapid dissolution and absorption of the active pharmaceutical ingredients contained in these tablets, providing a rapid onset of action. ODTs also provide specific advantages to pediatric and geriatric patient populations, which can sometimes experience difficulties in swallowing conventional tablets and capsules [1, 2]. A variety of different processes have been developed for the production of ODTs, including freeze drying and molding, as well as several other more conventional methods, including dry and wet granulation processes and direct compression [3].

The key challenges associated with the formulation of good ODTs include fast disintegration times, reasonably sized tablets, low moisture sensitivity and taste [4]. Given that the major criteria for the formulation of ODTs is a fast disintegration time, tables of this type usually include a large number of disintegrants, such as croscarmellose sodium (CCS or Ac-di-sol®) [5], crospovidone (CP) (Polyplasdone®) [6], sodium starch glycolate (SSG or Primogel®) [7], low-substituted hydroxy propyl cellulose (L-HPC) and pregelatinized starch [8]. Amino acids such as glycine, L-lysine and L-alanine can also be used as oral disintegration accelerators [9].

Ready-made mixtures of pharmaceutical excipients have recently been developed for different types of tablets with the aim of simplifying industrial formulation and tableting processes and reducing the manufacturing costs associated with the production of drugs and pharmaceutical agents.

The aim of this study was to compare the physical characteristics and dissolution properties of ODTs prepared using conventional methods with those prepared using a ready-made mixture of excipients (PROSOLV® ODT). These comparison experiments were conducted using levofloxacin as a model active pharmaceutical ingredient.

MATERIALS AND METHODS

Materials

Levofloxacin powder was kindly provided as a gift by JORIVER Pharmaceuticals (Amman, Jordan). Croscarmellose sodium (CCS or Ac-di-sol®), crospovidone (CP) (Polyplasdone®), sodium starch glycolate (SSG or Primogel®), mannitol, Acecil®, aspartame, talc, magnesium stearate and prosolv® ODT were kindly provided as gifts by HIKMA Pharmaceuticals (Amman, Jordan). Concentrated hydrochloric acid (37%) was purchased from Biosolve chimie SARL (Dieuze, France)

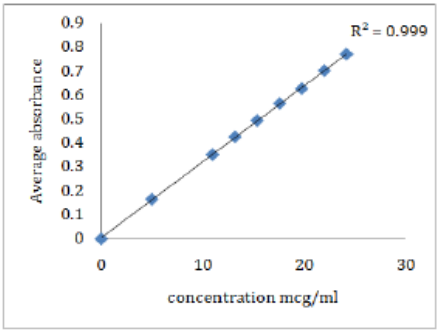

Fig. 1: Calibration curve for levofloxacin in 0.1 N HCl at 37±0.5 °C

Methods

Levofloxacin: method of analysis and calibration curve

As recommended by the International Conference on Harmonization (ICH) guidelines, the linearity of an analytical method should be determined using at least five different concentrations over a specified range of concentrations. In the experiments conducted in the current study, the linearity was determined by testing eight different concentrations of Levofloxacin in the range of 5–24.2 µg/ml (i.e., 5, 11, 13.2, 15.4, 17.6, 19.8, 22 and 24.2), with each individual concentration being tested in triplicate. The response at each concentration was represented by the UV absorbance, which was determined using a Jasco V 530 spectrophotometer (Jasco, Tokyo, Japan) with a λ_{max} value of 293 nm. The average absorbance values were plotted against concentration, and the results were subjected to the least square regression analysis, as shown in fig. 1.