Research Paper

Formulation and Evaluation of Gastro Retentive Drug Delivery System for Ofloxacin

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ABSTRACT: The purpose of this investigation was to prepare a gastroretentive drug delivery system of Ofloxacin. Ofloxacin is a fluoroquinolone antibacterial which acts by inhibiting the topoisomerase enzyme which is essential in the reproduction of the bacterial DNA. It is highly soluble in acidic media and precipitates in alkaline media thereby losing its solubility. Hence, a gastroretentive system was developed to enhance the bioavailability by retaining it in the acidic environment of the stomach. Different formulations were formulated using various concentrations of hydroxypropyl methyl cellulose, sodium carboxy methyl cellulose, sodium bicarbonate and citric acid. The formulations were evaluated for quality control tests and all the physical parameters evaluated are within the acceptable limits of Indian Pharmacopoeia. All the formulations were subjected to in-vitro dissolution studies and compared with the marketed formulation. The floating lag time was below 15 seconds for all the formulations except F1 and F2. The floating duration was found to be more than 24 hours in all except F1, F2 and F10. Formulations F7 and F8 were used to study the effect of sodium bicarbonate and formulations F9 and F10 for the effect of hardness on the drug release. Drug release kinetics was studied for prepared formulations and optimized formulation F5 was found to follow zero order kinetics with $r^2 = 0.993$. The statistical analysis of the parameters of dissolution data obtained before and after storage for 3 months at 25°C/60%RH and 40°C/75%RH showed no significant change indicating the two dissolution profiles were similar.

KEYWORDS: Ofloxacin, gastroretentive, floating tablets, controlled release.

Introduction

Novel oral controlled dosage form that is retained in the stomach for prolonged and predictable period is of major interest among academic and industrial research groups. One of the most feasible approaches for achieving prolonged and predictable drug delivery profile in the GI tract is to control gastric residence time (GRT). Dosage form with prolonged GRT or gastro-retentive dosage form (GRDF) provides an important option (S.S. Patel et al., 2006).

Retention of drug delivery systems in the stomach prolongs overall gastrointestinal transit time and improves the oral bioavailability of the drugs that have site-specific absorption from the stomach or the upper part of the small intestine. So, different approaches have been proposed to retain the drug in the stomach which includes bioadhesive systems, swelling and expanding systems, floating systems and delayed gastric emptying devices.

The principle of buoyant preparation offers a simple and practical approach to achieve increased gastric residence time for the dosage form and sustained drug release (M.N. Gambhire et al., 2007).

Gastrointestinal retention depends on many factors such as density of the dosage form, size of the dosage form, fasting and fed condition, nature of the meal, sleep, posture, etc. It also depends on a complicated and unpredictable gastric emptying with migrating myoelectric complex motility of the stomach (M.D. Chavanpatil et al., 2006). It was suggested that compounding narrow absorption window drugs in a unique dosage form with gastroretentive properties would enable an extended absorption phase of these drugs. Such a dosage form, after oral administration, would be retained in the stomach and release the drug in a sustained manner, so that the drug could be supplied continuously to its absorption sites in the upper gastrointestinal tract (M. Chavanpatil et al., 2005).

Ofloxacin exhibits pH dependant solubility. It is more soluble in acidic pH and slightly soluble in neutral or alkaline pH conditions (intestinal environment). In the intestine, however, precipitation of the drug occurs, which adversely affects the absorption in the lower sections of the