Commentary Article

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Preparation and Evaluation of Ciprofloxacin Hydrochloride Swellable Gastroretentive Tablets

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Description

Most of the drugs which are found to have narrow spectrum of absorption index in the GIT i.e. Gastro-Intestinal Tract show reduced absorption. Thus, it is essential to extend the residence time of such drugs in gastric region. Ciprofloxacin HCl is a Chloroquinolone antibiotic drug which is found to have a narrow absorption window, small elimination half-life and is mostly absorbed in proximal parts of GIT. The aim of this work was to formulate a Gastro Retentive Drug Delivery System (GRDDS) with floating and swelling capacity. It is effective against Helicobacter pylori bacteria which causes peptic ulcer. Hence, it is necessary to upsurge the Gastric Retention Time (GRT) of such drugs. In this study, 12 different formulations of ciprofloxacin HCl swell able and floating gastro retentive tablet were formulated using wet granulation process. Then, all these formulations were evaluated for pre-compression parameters as well as post-compression parameters like visual inspection, weight variation, hardness, friability, content uniformity, thickness, buoyancy studies *i.e.* Floating Lag Time (FLT) and Total Floating Time (TFT), swelling index, dissolution and drug release kinetics. Based on the evaluated result, the F6 formulation was found to be the best formulation as it contains API Ciprofloxacin HCl (580 mg), polymer-HPMC K100M (116 mg), swelling agent SSG (232mg) and sodium bicarbonate as effervescent agent.. It showed swelling index time of 242 % in 4 hr, FLT of 310 sec, TFT of more the 7 hour and the drug release kinetics followed Higuchi Model.

Gastro retentive Drug Delivery System

The oral delivery system is one of the best preferred means of oral drug delivery due to patient compliance, comfort in administration and simple preparation. The developed or designed Floating Drug Delivery System (FDDS) is primarily with the aim to achieve prolonged bioavailability and gastric emptying time (typically 2-3hrs) via first stomach absorption area or upper portion of the intestine [1]. The oral route is the well-known route and support for various drugs. GRDDS is a way to extend GRT by directing site-specific drug discharge within GIT for systemic or local effects [2]. These dosage forms can stay within the gastric environment for prolonged time and consequently delay the GRT of medicines. GRDDS fused and established with sellable structures delay exhausting of the dosage form from pyloric sphincter of the GIT. GRDDS are set up with the aim to hold drug within GIT for a longer duration and treatment. Longer residence of the drug in the upper part of the GIT successively provides good bioavailability [3]. FDDS is among the significant way to provide better gastric and get appropriate drug bioavailability. After drug release, the remaining drug is deflated from stomach and results in an increased GRT [4].

The real challenge in the development of GRDDS is not only to support drug release but also to increase the availability of dosage form within GIT until entire drug is completely released in a timely manner [5]. Certainly, the preservation of drug in stomach has gained much interest in the last few decades [6]. Most conventional oral delivery dosage forms have shown some limitations related to the immediate duration of gastric emptying [7].

The chemicals used for the formulation of ciprofloxacin hydrochloride floating tablets were Ciprofloxacin hydrochloride (as drug), HPMC as a hydrophilic polymer (K15M and K100M), crosscarmellose sodium, crosspovidone, SSG as a swelling agent, and sodium bicarbonate as an effervescent agent. All the chemicals were purchased from R.K. Enterprises, Meerut (CDH) and were of laboratory grade.

Pre-Formulation Study of Drug

This is the first step in the development of any type of API or dosage form. The word “reformulation” on its own defines its meaning as ‘pre’ refers to work that must be done before the development of any dosage form [8]. It includes research into the physical and chemical properties of individual active drug, as well as their combinations with auxiliary substances [9]. Therefore, the purpose of pre-medicine training is to know about the key facilitator's knowledge of designing a stable and effective composition [10]. Preliminary studies are conducted to understand the basic drug profile, e.g. drug efficacy, drug bioavailability, pharmacokinetic and pharmacodynamics properties or any unwanted drug reactions [11].

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