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Novel gastroretentive formulation of an Ayurvedic churna for peptic ulcers: Optimization and evaluation

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ABSTRACT: Avipattikar churna is well known Ayurvedic formulation in India for Amalpitta. Voluminous dose leading to poor patient compliance, less residence time in stomach and less stability are the major limitations of the Churna. Thus, the objective of research work was to develop a novel gastroretentive floating drug delivery system of Avipattikar churna. The churna was prepared and evaluated for phytochemical analysis. The main constituents, Jalap, and Clove, contained scopoletin and eugenol as active markers. A floating tablet of Avipattikar churna was optimized using a 3^2 factorial design, with HPMC K4M and HPMC K100M concentrations as independent factors and floating lag time (FLT) and % release of scopoletin and eugenol at 1 h, at 4 h and at 8h as dependent variables. The optimized formulations were evaluated by physical parameters. The optimized formulation was selected based on factorial design and numerical desirability Index values. *In-vitro* dissolution study was performed for optimized formulation and compared with marketed Avipattikar churna. Release mechanisms of markers were determined using various kinetic models and DD solver. The stability studies followed ICH guidelines. The preliminary trial batches were formulated by using direct compression method. 15% of the mixture of HPMC K100M and HPMC K4M was finalised based on the factorial design results and desirability index. Optimized formulation showed FLT of 88 ± 0.3 sec, with cumulative eugenol release at 1h (18.78%), 4h (60.23%), and 8h (95.36%). Scopoletin cumulative release was 21.43%, 68.51%, and 89.34% at 1h, 4h, and 8h, respectively. In a release kinetics, formulation showed diffusion mechanism followed by anomalous diffusion. The formulation was stable as revealed by 3 months accelerated stability studies as per ICH guidelines. From the experiments, 15% of HPMC K100M and HPMC K4M gave shorter floating lag time, good consistency and extended the duration of drug release over time frame of 8h. The formulation was found to be stable.

KEYWORDS: Gastroretentive floating tablet; Avipattikar churna (An Ayurvedic classical formulation); 3^2Factorial design; Drug release

1. INTRODUCTION

In Ayurveda, the treatment of Avipattikar Churna was found to be effective in treating peptic ulcers and GI-related problems like hyperacidity, piles, etc [1] (Ayurvedic pharmacopoeia of India 2007). The formulation was to have cytoprotective action, decreasing acid secretion and promoting mucus production and mucosal resistance. It was also shown aid in maintaining the basal blood flow to the gastrointestinal mucosa [2-6].
To overcome the limitations of Ayurvedic churna, Alternative dosage forms are essential that can be easily administered, provide patient compliance, and also provide gastroprotective action [7].
The oral route is recommended method of pharmaceutical administration because it offers low administration difficulty, the correct dose, a precise, flexible dosing schedule, self-medication, and desirable patient compliance [8, 9]. A better way to deal with these issues could be to produce gastro-retentive formulations to ensure patient compliance, ease of administration and reducing dose. A prolonged release of the drug is made possible by FDDS (floating drug delivery systems) having lower bulk density in comparison to gastric fluids and hence float in the stomach without slowing down the gastric emptying rate [10, 11]. More specifically, CO2 gas is produced by the effervescent varieties of floating drug delivery systems, which lower the density of the system and allow it to float in the stomach for a prolonged period of time while gradually releasing the drug at a sustained and constant rate [12, 13]. These medication delivery systems are designed to provide medication to the upper gastrointestinal tract over a sustained period of time [14, 15].

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