ABSTRACT

The current research effort highlights the development and evaluation of novel drug delivery system of selective H2 receptor antagonist. Nowadays buccal delivery focused much interest in which buccal mucosa as a route of administration in an attractive manner. Mucous membrane favors several advantages such as relative permeability, robustness and sudden recovery after damage is possible with this delivery systems. The performance of many drugs is improved by using bioadhesive polymers, in which tissues are been in prolonged contact with these polymers. In H2 receptor antagonists Famotidine, a choice of drug used in the treatment of Zollinger-Ellison syndrome and gastro-esophageal reflux disease, widely prescribed in gastric ulcers, duodenal ulcers. The bioavailability of Famotidine following oral administration is 40-45%, and has a shorter plasma half life (2.5-4.0 h) due to first pass metabolism.

The solvent casting technique was used in the preparation of buccal films with different polymer combinations of hydroxy propyl methyl cellulose-K4M, carbopol-934P and poly vinyl pyrrolidone. The fabricated films were evaluated for their physiochemical characters such as weight, thickness, folding endurance, surface pH, percentage moisture absorption, percentage moisture loss, swelling percentage, water vapor transmission, drug content and mechanical strength. The novel Famotidine buccal tablets prepared mainly by using direct compression method with mucoadhesive polymeric materials such as Sodium alginate, SCMC, HPMC K-100, Eudragit-RL100 and Poly vinyl pyrrolidone. Ethyl cellulose acts as a backing layer to prevent release of drug into saliva of buccal cavity. The powder material was used to study different parameters like Bulk density, tapped density, hausner’s ratio, Angle of repose and also Carr’s index. The buccoadhesive tablets were characterized on their physicochemical parameters in which friability thickness, hardness, weight variation, drug content, surface pH are considered and observed. The results obtained are mainly depend and vary on the composition and characteristics of the materials used. Ex-vivo mucous irritation by histological examination reveals, the administration site of buccal tablet and buccal film over the
buccal mucosa did not cause any irritation, ulceration, inflammation and redness, and it resembles to controlled buccal mucosa. By maintaining accelerated conditions, stability studies were been performed using human saliva and it has shown no difference in physical characters, content of drug, buccoadhesive strength, the $P$-value statistically significant at $<0.05$. The basic pharmacokinetic parameters mainly plasma concentration, maximum plasma concentration and total area under the plasma concentration-time curve are measured by using the plasma concentration-time profiles data. In-vivo kinetics was shows in the extent of bioavailability and in the rate of absorption. In-vitro and ex-vivo, in-vitro and in-vivo drug release showed good correlations. Diffusion of drug from buccal films and buccal tablets showed kinetics of zero order and diffusion mechanism was followed after considerable swelling.

The Famotidine mucoadhesive hydrogel beads were prepared by orifice ionotrophic gelation method is well suited for the successive formulations. The polymers and solvent were chosen has showed more percentage yield of hydrogels. The polymer used as sodium alginate, HPMC K100, SCMC and carbopol for the formulation of hydrogels shows no significant interaction. The physicochemical properties were characterized by Swelling index, water uptake studies, gel fraction, Size analysis, yield of percentage, content amount of drug and Drug entrapment efficacy. For all the formulations in-vitro release studies were performed and they shown the controlled release pattern of drug up to 11 h. Surface morphological studies by SEM analysis obtained showed good spherical shape and also surface morphological characters. The release rate of in-vitro studies was compare with that of the marketed formulation. The satisfactory results were obtained in all prepared formulations and based on the results H13 was best one when compared to other. In-vitro and In vivo studies have shown good correlation and they revealed ability of the formulation to reproduce the in-vitro release pattern. Hence Famotidine oral mucoadhesive hydrogel beads which are used mainly in minimizing dose and mainly help to improve the patient compliance and Famotidine is a drug of choice for delivery through the control release via mucoadhesive hydrogels.