Development of Mucoadhesive Buccal Films of Glipizide

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ABSTRACT: For improving bioavailability in controlled release fashion and to circumvent the hepatic first pass effect of glipizide mucoadhesive buccal films of glipizide were prepared by solvent casting technique. Buccal films were prepared using hydroxy propylmethylcellulose, sodium carboxymethylcellulose, carbopol-934P and Eudragit RL-100. Films were evaluated for their weight, thickness, surface pH, swelling index, in vitro residence time, folding endurance, in vitro release, ex vivo permeation studies and drug content uniformity. The films exhibited controlled release over more than 6 h. From the study it was concluded that the films containing 5 mg glipizide in 4.9 % w/v hydroxy propylmethylcellulose and 1.5 % w/v sodium carboxymethylcellulose exhibited satisfactory swelling, an optimum residence time and promising drug release thus proved to be potential candidate for the development of buccal films for therapeutic use.

KEY WORDS: Mucoadhesive, Buccal Film, Glipizide, In Vitro Studies, Ex Vivo Studies.

Introduction

Amongst the various routes of administration tried so far for novel drug delivery systems, localized delivery to tissues of the oral cavity has been investigated for a number of applications including the treatment of toothaches (Ishida et al., 1982) periodontal disease (Collins et al., 1989, Elkayam et al., 1988), bacterial and fungal infections (Samaranayake et al., 1989), aphthous and dental stomatitis (Nagai, 1985), and in facilitating tooth movement with prostaglandins (Nagai and Machida, 1985). Over the last two decades mucoadhesion has become of interest for its potential to optimize localized drug delivery, by retaining a dosage form at the site of action (e.g. within gastrointestinal tract) or systemic delivery, by retaining a formulation in intimate contact with the absorption site (e.g. the buccal cavity). Mucoadhesion maybe defined as a state in which two materials, one of which is mucus or a mucous membrane, is held together for extended period of time (Smart, 2005, Ahuja et al., 1997). Various studies have been conducted on buccal delivery of drugs using mucoadhesive polymers (Smart, 2005, Shojaei, 1998). Recently some scientists (Jasti et al., 2003, Salamat-Miller et al., 2005, Semalty, 2006) have reviewed the use of mucoadhesive polymers in buccal drug delivery and highlighted the use of novel mucoadhesive polymers. Attempts have been made to formulate various mucoadhesive devices including tablets (Ali et al., 1998), films (Kohda et al., 1997), patches (Nair and Chien, 1996, Perioli, L., et al., 2004), disks (Parodi et al., 1996, Ali et al., 2002), strips (Ilango et al., 1997), ointments (Bremecker et al., 1984), and gels (Shin et al., 2000). Buccal film may be preferred over adhesive tablet in terms of flexibility and comfort. In addition, they can circumvent the relatively short residence time of oral gels on the mucosa, which are easily washed away and removed by saliva. Moreover, the buccal films are able to protect the wound surface, thus reducing pain and treating oral diseases more effectively (Nafee et al., 2003).

Glipizide is a second generation sulfonylurea compound used as an oral hypoglycemic or antidiabetic agent. Glipizide is one of the most potent of the sulfonylurea antidiabetic agents. It is 100 times more potent than tolbutamide in evoking pancreatic secretion of insulin. It differs from other oral hypoglycemic drugs in that tolerance to its action apparently does not occur. It also upregulates insulin receptors in the periphery, which seems to be the primary action. Its short biological half-life (3.4 ± 0.7 hours) necessitates its administration in 2 or 3 doses of 2.5 to 10 mg per day. Moreover, about 90% of the drug is metabolized in the liver forming several inactive metabolites (Foster and Plosker, 2000). Thus an attempt has been made to develop a buccal mucoadhesive dosage form of glipizide for improving and enhancing bioavailability in controlled release fashion. It may also be possible to circumvent the hepatic first pass effect by administering the drug through buccal mucosa.

The present work deals with the formulation and characterization of mucoadhesive buccal films of glipizide using mucoadhesive polymers like Hydroxy propylmethylcellulose, Carbopol-934P, Eudragit RL-100 and Sodium carboxymethylcellulose.

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