

Design and in vitro/in vivo evaluation of ultra-thin mucoadhesive buccal film containing fluticasone propionate.

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Abstract

Fluticasone propionate is a synthetic corticosteroid drug distinguished by its potent anti-inflammatory action with low systemic side effects in comparison to other corticosteroids making it a potential drug for local buccal delivery. The aim of the present study was to design mucoadhesive buccal film containing fluticasone that is aesthetically acceptable and could maintain local drug release for a sustained period to manage the sign and symptoms of severe erosive mouth lesions. Solvent casting technique was used in film preparation. Different polymeric blends were used either alone or in combination with mucoadhesive polymers, sodium carboxymethyl cellulose (SCMC), or Carbopol 971P at different concentrations. The physicochemical properties, in vitro mucoadhesion time as well as the drug release properties for all prepared formulations were determined. Selected formulations with adequate properties were further examined by differential scanning calorimetry (DSC) and X-ray diffraction (XRD) and subjected to in vivo evaluation. Films containing hydroxypropyl methylcellulose (HPMC)/ethyl cellulose (EC) showed acceptable physicochemical properties, homogenous drug distribution, convenient mucoadhesion time, moderate swelling as well as sustained drug release up to 12 h. The biological performance of these formulations was assessed on healthy human volunteers and compared with a prepared mouthwash which showed enhanced pharmacokinetic parameters for the selected films in comparison to the mouthwash. The results revealed that the optimized formulation containing HPMC/EC and 10% SCMC could successfully achieve sustained drug release for 10 h which is considered promising for local treatment of severe mouth lesions.

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