Formulation and clinical evaluation of mucoadhesive buccal films containing hyaluronic acid for treatment of aphthous ulcer

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Abstract

Hyaluronic acid (HA), a linear polymer of glucuronic acid N acetyl glucosamine disaccharide, has tissue healing properties and is used for treatment of oral ulcers. This study aims to develop a controlled release mucoadhesive buccal film containing HA as a novel delivery system to overcome the drawbacks of the fast wash off of mouth rinses and gels used for treatment of aphthous ulcers. HA films are prepared by applying freeze and thaw cross linking technique. A full 21 Ĭ 31 Ĭ 41 factorial design was applied to study the effect of three independent variables namely polymer type, polymer concentration and the number of freeze/thaw cycles on the selected dependent variables of tensile strength, mucoadhesion and time required to release 50% of HA (T50%). The prepared HA films were evaluated for their physicochemical properties including folding endurance, surface pH, thickness, mucoadhesion properties, tensile strength and in vitro drug release. The optimum formula was evaluated for its clinical efficiency in treatment of patients have aphthous ulcer. The obtained results (good physical properties, mechanical properties (high TS), mucoadhesion properties and controlled release (high t50%)) indicated that an optimum formula for controlled release mucoadhesive buccal film which is aimed to be effective, safe and stable when used in treatment of aphthous ulcers. After clinical study, it was observed that the formulation of the hyaluronic acid resulted in a more potent effect and resistance to the washing effect of saliva and friction from food. The efficacy of hyaluronic acid was greatly affected by formulation which allowing for prolonged contact.

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