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Preparation and Estimation of Ebastine Orodispersive Tablets Using Natural Super Disintegrant by Molecular Dispersion Technique

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Abstract

Ebastine is a 2nd generation H1 receptor antagonist that is mainly indicated for allergic rhinitis and chronic idiopathic urticaria. In allergic conditions the patient become panic and will have difficulty to swallow tablet with a glassful of water. In such cases Orodispersive tablets will be a good solution for patient compliance and efficient dose regimen. Ebastine tablets are available in different strength i.e. 10 mg and 20 mg. The main objective of this project work was to developed and designed an Orodispersive tablets (ODTs) containing Ebastine 20 mg, using “Natural Super Disintegrants” by molecular dispersion technique including various pharmaceutical excipients with different strengths to enhance patient compliance and therapeutic value as compare with the available market brands. Orodispersive Tablets of Ebastine were formulated by molecular dispersion technique and using Natural Superdisintegrants such as Agar and Guar gum and other excipients like gelatin, sodium lauryl sulphate, microcrystalline cellulose, sweetening agent as Sodium saccharine, talc and magnesium stearate as lubricants, clove oil and lemon flavor as flavoring agent. Drug - excipients compatibility tests performed before start the formulation. The selection and the rejection of excipients for experimental formulation was considered after getting the result of drug excipients compatibility study. The flowability of the powder mixtures were evaluated using Carr's index, Angle of Repose and the Hausner's ratio. The tablets were evaluated according to the standards prescribed by British Pharmacopoeia like weight variation, thickness, hardness, friability, disintegration time, a simulated wetting test and in-vitro dissolution. Prepared tablets after Optimization showed disintegration time less than 30 seconds and drug dissolution of about 75% within 30 minutes. The prepared tablets of optimized batch tested for stability 40 degree Celsius and 75% RH for 3 months and were found to be stable. Prepared Orodispersive tablets of Ebastine 20 mg from optimized batch were found bioequivalent under fasting and fed conditions with the available market products. The determination and evaluation were made for the most effective type and optimal amount of “Natural Super Disintegrants” for the manufacture of Orodispersive Tablets by molecular dispersion & direct compression technique.

Keywords

Ebastine, Molecular Dispersion, Disintegrant, Orodispersive

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