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Thesis Abstract

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DISSOLUTION RATE ENHANCEMENT OF BCS CLASS II DRUGS BY ORDERED MIXING

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ABSTRACT

Ordered mixtures were achieved by dry mixing coarser carrier particles with fine drug particles so that fine drug particles adhere to the surface of carrier particle by adhesion forces. Five different water soluble carrier (lactose, mannitol, sorbitol, maltitol and sodium chloride) materials were used to prepare granules along with superdisintegrant (sodium starch glycolate) and surfactant (sodium lauryl sulphate). Absolute ethanol was used as granulating liquid to prevent swelling of the superdisintegrant. Ordered mixtures of the granules and BCS class II model drug (piroxicam or gliclazide) were prepared in a glass vial by manual hand shaking method. The prepared ordered mixtures were evaluated for dissolution rate enhancement. Suspensions of the drugs were used as reference. The effect of drug strength, particle size of granules and formulation variables on the dissolution rate of the drugs were studied. Selected formulations of ordered mixtures were compressed to tablets followed by animal studies to ascertain the effect of dissolution rate enhancement of the efficacy of the drug. The dissolution rate of drug from ordered mixtures of granules containing highly soluble sugar (lactose) and sugar alcohols (mannitol, sorbitol, maltitol) was found greater than the suspension. Sodium chloride was found least effective in dissolution rate enhancement when compared to other excipients used as carrier materials. Highly soluble carrier materials gave an extremely fast dissolution of the drug, even faster than from a well-dispersed suspension. The synergistic effect of water soluble excipients, superdisintegrant and surfactant in dissolution rate enhancement was observed. Furthermore, the effect of addition of fine carrier particles to ordered mixture was found to be effective marginally in dissolution rate enhancement. The prepared ordered mixtures gave comparable dissolution rate profiles when dissolution rate studies were conducted at different rpm of paddles in the dissolution apparatus. It was anticipated that rapid dissolution of the carrier particles left the drug as well dispersed primary particles leading to faster dissolution which remained unaffected by the stirring of the dissolution medium.

The ordered mixtures were compressed to tablets by incorporating MCC as filler, sodium starch glycolate as disintegrant and magnesium stearate as lubricant. Tablets consisted majority portion of the ordered mixtures which in turn consisted of water soluble excipients. Acceptable tablets were obtained only with mannitol and sorbitol while lactose gave friable tablets which failed at hardness and friability. The best tablets were achieved with ordered mixtures consisting of sorbitol as water soluble excipients. The dissolution rate of all the prepared tablets was found comparable to ordered mixtures which indicated that compression did not negatively influenced dissolution rate of drug. Animal studies proved that the effect of the drug in the formulation was more than the commercially available tablets.

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