Oral Rapid Dissolving Films as Delivery Systems for Cetirizine hydrochloride

A Thesis submitted in partial fulfillment of the requirements for the Master Degree of Pharmaceutical Sciences (Pharmaceutics)

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القاهرة

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Abstract

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Cetirizine (CTZ) rapid dissolving films were prepared by solvent casting method. For masking the bitter taste of CTZ, a drug resinate complex using cation exchange resin amberlite IRP 64 in the ratio 1: 3 (drug to resin) was prepared using batch process method. Taste masked CTZ resin complex powder was subjected for taste evaluation, FTIR spectroscopy, differential scanning calorimetery (DSC), X ray diffraction analysis (XRD), drug content determination and in vitro drug release.

A 2 X 3 X 6 full factorial design was built up for the preparation of optimized rapid dissolving film formula. The factors were the plasticizer type at 3 levels, viz 10% w/w of each of polyethylene glycol 400 (PEG 400), propylene glycol (PG) and glycerin, the film forming material (polymer) concentration at 2 levels: 1 and 2% w/v and the polymer type at 6 levels, viz hydroxypropyl methyl cellulose (HPMC), hydroxypropyl cellulose HPC, HPMC/HPC (1:1 w/w), HPMC/sodium carboxymethyl cellulose (Na CMC) (1:1 w/w), HPC/Na CMC (1:1 w/w) & HPMC/HPC/Na CMC (1:1:1 w/w). The responses measured were: tensile strength, folding endurance and *in vitro and in vivo* disintegration. To improve the film characteristics, various concentrations : 10, 30 and 60 % (w/w of dry polymer) of the best plasticizer were tried against the chosen polymer. Finally and for further optimization, the effect of disintegrants such as sodium starch glycollate and croscarmellose sodium in three different concentrations: 25, 35 & 45% (w/w of dry polymer) was studied. The visual evaluation, ease of peeling from the plate, thickness, tensile strength measurement, folding endurance, *in vitro* disintegration

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