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Research Paper

Formulation and Characterization of Mouth Dissolving Tablets of Ezetimibe by Frosta Technique Using Ezetimibe: Hydroxypropyl-β-cyclodextrin Solid Dispersion

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Highly plastic granules that can be compressed into tablets at low pressure were developed to make mouth dissolving tablets (MDTs) by compression method. In formulation of MDTs by Frosta technique, perlitol SD 200, maltrin QD M 580 and sucrose solution (40% W/V) were used as plastic material, water penetration enhancer and a wet binder respectively. Maltrin QD M 580 and pearlitol SD 200 were mixed in different proportions (10:90, 20:80, 30:70, 40:60 and 50:50). Wet binder (sucrose solution, 40% w/v) was used because it preserved the porous structure of maltrin QD M 580 and give better mechanical strength. Mouth dissolving tablets (batches MT1-MT5) were prepared by wet granulation method using optimized Ezetimibe: Hyroxypropyl-β-cyclodextrin solid dispersion (1:3 ratio, Batch SD3). The prepared Ezetimibe: Hyroxypropyl-β-cyclodextrin solid dispersion were characterized by Fourier transform infrared spectroscopy, differential scanning calorimetry, and powder X-ray diffraction and reveals reduction in drug crystallinity which might be responsible for improved dissolution properties. Evaluation of the tablets showed that all the tablets were found to be within official limits and the optimized batch MT3 (Containing 30% maltrin QD M 580 and 70% pearlitol SD 200) exhibited a disintegration time of 13.67 sec, percentage friability of 0.435%, wettability of 12 sec and 99.88 % drug release at the end of 45 minutes. The stability study conducted as per the ICH guidelines for six months and the formulations were found to be stable. The results concluded that mouth dissolving tablets of Ezetimibe successfully prepared by Frosta technique and improve the bioavailability of drug.

Key words: Ezetimibe, Hyroxypropyl-β-cyclodextrin, Maltrin QD M 580, Mouth dissolving tablet, Frosta Technique.

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