Thesis Title Effect of Cetyl Alcohol as a Matrix Material on the Controlled Release of Propranolol Hydrochloride.

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ABSTRACT

Lipids have been employed as a solid matrix to prolong release of drug, oweing to its insolubility, integrity in dissolution medium and nontoxic. In this study, the matrix system composed of propranolol hydrochloride and cetyl alcohol was prepared in the multiparticulate form of granules to investigate the effect of cetyl alcohol on the release of propranolol hydrochloride. The granules were prepared by two different methods at various ratios of drug to carrier. Method I: the drug was dispersed in the melting wax and sized to granules after solidification. Method II: the granule was prepared in the same manner as in I but granules were spheronized by rolling in the coating pan and blow intermittantly with hot air. The granules were classified to three fractions, i.e., 8/10 , 10/18 and 18/30 mesh. The dissolution of these

prepared by method I released the drug rapidly, 90% within 1.5 hours. However, the granules prepared by method II could prolong the release of drug upto 12 hours and met the USP XXII dissolution requirement on the extended - released propranolol hydrochloride capsule. Furthermore, the dissolution rate was depended on the ratios of drug : wax, granule size and dissolution medium. The release kinetic of spheronized granules dictated by diffusion control in both acid and basic medium. From DSC study, propranolol hydrochloride probably dissolved in cetyl alcohol at high temperature. Therefore, the melting temperature and the holding time during manufacturing process should be controlled.