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FORMULATION AND DRUG RELEASE STUDIES FROM CONTROLLED-RELEASE IBUPROFEN TABLETS PREPARED WITH AQUEOUS DISPERSION OF ETHYLCELLULOSE

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ABSTRACT:

The objective of this study was to investigate the potentials of a cellulose based aqueous polymeric dispersion, Surelease®,in the formulation of controlled-release (CR) tablets of a sparingly water-soluble drug, ibuprofen (IBF). Tablets were prepared by wet granulation method incorporating Surelease® as a granulating agent. Dissolution experiments were performed by the USP Method I (rotating Basket) in dissolution media with different pH environments. The f_2-metric technique was employed for the determination of the dissolution equivalency and various types of kinetic models were exploited to analyze the release profiles through multiple linear regression computer software programs. The influence of certain parameters and variables such as drug loading, drug-to-polymer (D:P) ratio in the granulations, crystalline form of IBF, tablet hardness, annealing conditions of the granulations, pH of the dissolution media, selected dissolution method, agitation speed, and partial replacement of the primary excipient with various types of coexcipients such as microcystalline cellulose (MCC), starch, polyvinylpyrrolidone (PVP), sodium alginate, hydroxypropyl methylcellulose (HPMC), and sodium carboxymethyl cellulose (CMC-Na) on the release rates and kinetics of IBF from the tablets were evaluated. In general, tablet prepared with Surelease® as granulating agent were non-disintegrating and exhibited prolonged drug release rates with pH independent release profiles. Drug loading and Surelease® solids content (SSC) ratio in the tablets resulted in retardation of drug release rates in concentration dependent manners. Release profiles were also affected differently by the crystalline form of IBF and