FORMULATION DEVELOPMENT AND EVALUATION OF SILDENAFIL CITRATE ORAL THIN FILMS

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Abstract

To discover and develop a newchemical entity or moleculeor drug is atime taking and an expensive process. Hence the industries especially in pharmaceutical field, are concentrating to develop innovative concepts for existing drugs. Fast dissolving drug delivery systems (FDDDSs) have acquired an important position in the market by overcoming the problems posed by other routes of administration of drugs. FDDDSs have the unique property of rapidly disintegrating and/or dissolving and releasing the drug as soon as they come in contact with the saliva.One of such advanced drug delivery system is oral thin film. Sildenafil citrate, a drug used to treat erectile dysfunction, is available in tablet form in market but has some biopharmaceutical problems i.e. poor solubility, low bio-availability, extensive first pass metabolism and also affect gastrointestinal tract (dyspepsia and burning sensation).The aim of the present work is to develop and evaluatesildenafil citrate oral thin films. The oral thin films are prepared by solvent casting method using drug (sildenafil citrate), film former (hydroxypropylmethyl cellulose E5), glycerine, plasticizer (polyethylene glycol), and water. The blank films were evaluated in respect to their*in vitro* disintegration and tensile strength. The blank film of optimum polymer and plasticizer (hydroxypropylmethyl cellulose E5 and polyethylene glycol) ratio has been chosen and then loaded with sildenafil citrate. All the formulations (F1 to F9) were subjected to pre-formulation studies, like drug excipient compatibility studies, morphology, swelling index, *in vitro* disintegration.The present work emphasizes on potential benefits, design, development of robust, stable, innovative, orally fast disintegrating films and their future scenario on a global market as a pharmaceutical dosage form.