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Design and evaluation of press coated pulsatile release tablets of prednisolone

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To formulate and evaluate a press coated pulsatile release tablets of prednisolone using an admixture of hydrophilic polymer, i.e., low substituted hydroxy propyl cellulose (L-HPC) and hydrophobic polymer, i.e., ethyl cellulose (Ethocel 10 cps) in order to achieve a pre-determined lag time for chronotherapy of rheumatoid arthritis. The press coated pulsatile tablets containing prednisolone in the inner core were prepared by compression coating with L-HPC and Ethocel 10 cps as the outer layer in different ratios. The effect of polymer ratio and weight gain of the outer layer on lag time of drug release was investigated using 32 full factorial design. The parameters determined were tablet hardness, friability, drug content, lag time, *in vitro* dissolution. The release profile of the press coated tablet exhibited a distinct lag time before burst release of prednisolone. Lag time was dependent on the ratio of L-HPC/Ethocel 10 cps and weight gain in outer shell. The lag time was from 1 to 10 hr and could be modulated as it decreased as the amount of L-HPC in the outer layer increased. A surface plots are also presented to graphically represent the effect of independent variables on the lag time. The validity of generated mathematical model was tested by preparing checkpoint formulation. Formulation PCPT7 with L-HPC/Ethocel 10 cps (10:90) and weight gain 300 mg showing predetermined lag time of 5 hr prior to burst release of the drug from the press coated tablet was taken as the optimized formulation.

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