Development and in vitro/in vivo evaluation of etodolac controlled porosity osmotic pump tablets

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Abstract

The aim of the current work was the design and evaluation of etodolac controlled porosity osmotic pump (CPOP) tablets exhibiting zero order release kinetics. Variables influencing the design of (I) core tablets viz., (i) osmogent type (sodium chloride, potassium chloride, mannitol and fructose) and (ii) drug: osmogent ratio (1: 0.25, 1: 0.50 and 1: 0.75)] and (II) CPOP tablets viz., (i) coating solution composition, (ii) weight gain percentage (1 – 5%, w/w) and (iii) pore former concentration (5, 10 and 20%, v/v)] were investigated. Statistical analysis and kinetic modeling of drug release data were estimated. Fructose-containing core tablets showed significantly ($P < 0.05$) more retarded drug release rates. An inverse correlation was observed between drug: fructose ratio and drug release rate. Coating of the optimum core tablets (F4) with a mixture of cellulose acetate solution (3 %, w/v), diethyl phthalate and polyethylene glycol 400 (85: 10: 5 v/v, respectively) till a 4% w/w weight gain enabled zero order-sustained drug delivery over 24 h. SEM micrographs of coating membrane confirmed pore formation upon contact with dissolution medium. When compared to the commercial immediate release Napilac® capsules, the optimum CPOP tablets (F4 - 34) provided enhanced bioavailability, extended duration of effective etodolac plasma concentration with minimum expected potential for side effects in healthy volunteers.

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