

Formulation and Evaluation of Floating Beads for Chronotherapy of Hypertension

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Abstract

Preparation of multiple unit floating pulsatile beads of Carvedilol by simple ionotropic gelation method intended for chronotherapy of hypertension. Pectin and sodium alginate were used as matrix forming polymer and NaHCO₃ was used as floating agent. Simple acid- base reaction was formed in the generation of the CO₂ gas for Floating. A 2³ full factorial design was applied to investigate the combined effect of three independent formulation variables namely amount of sodium alginate, sodium bicarbonate and CaCl₂ on the dependent variables as % entrapment efficiency, floating lag time and % drug release in 0.1N HCl. Drug loaded multiparticulates were evaluated for various parameters like particle size measurement, flow properties, % drug entrapment, floating study, and dissolution study. Based on minimum drug release in 0.1 N HCl and after 6 h lag time period and maximum release in 6.8 pH phosphate buffer by burst release within 45 minutes, formulation containing 300 mg sodium alginate, 225 mg sodium bicarbonate and 4 % of CaCl₂ was optimized and tested for drug release pattern, floating lag time and entrapment efficiency. Surface response plots were presented graphically to represent the effect of independent variables on floating lag time, entrapment efficiency and drug release in 0.1 N HCl. The validity of the generated mathematical model for each response was checked by

preparing three extra-design check point batches and the comparable results of predicted and actual values validated the design. Stability (at 40^o/75% relative humidity for 1 month) studies on the formulation indicated that there were no significant changes in drug content, floating lag time, entrapment efficiency and drug release in 0.1 N HCl. Thus, the floating beads were successfully formulated for chronotherapy of hypertension giving site- and time specific release of drug.