

Development and in vitro evaluation of domperidone/Dowex resinate embedded gastro-floatable emulgel and effervescent alginate beads

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Abstract

This work aims to develop and evaluate buoyant beads embedded with domperidone/Dowex 50WX2 resinate complex as novel multiple-unit type oral gastro-retentive drug delivery system. Domperidone (BCS II) has been chosen for gastric retention as it has a poor oral bioavailability (around 15%), a short biological half-life, and pH-dependent solubility with poor solubility at a high pH and good solubility at low pH. Two different techniques were used to induce beads buoyancy; first, formulation of effervescent beads by incorporation of NaHCO₃ in the beads, which will release carbon dioxide gas upon reaction with the acidic gastric fluid causing the beads to float. Second, is the formation of low-density emulgel beads by the incorporation of light mineral oil in the beads. Resinate complex is used to control the drug release from the prepared formulations. Beads were evaluated for percent drug entrapment efficiency, floating behavior (float lag time and duration), mean particle diameter, in vitro drug release, and release kinetics in SGF. The effect of different concentrations of both NaHCO₃ (1%, 2%, and 10%) and light mineral oil (2%, 5%, and 10%) on the floating behavior and physical appearance was studied. The optimized formula (F10) was subjected to a four-week stability study at both 25°C and 40°C. Floating duration of up to 24 h and no floating lag time was developed. The novel resinate loaded beads succeeded to sustain the release of domperidone in SGF. The optimized formula was stable at both temperatures of 25°C and 40°C for 4 weeks. Hence, the developed optimized formulation (F10) is considered as a potential to increase the domperidone bioavailability, decrease dosage frequency, and increase patient compliance.

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