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Preparation and characterization of calcium silicate based floating microspheres of famotidine for treatment of peptic ulcer

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The aim of the present study was to prepare and evaluate floating microspheres consisting of (i) calcium silicate (CS) as porous carrier; (ii) famotidine and (iii) hydroxypropyl methylcellulose (HPMC) and ethylcellulose (EC) as polymers. The floating microspheres were evaluated for particle size, micromeritic properties, percent drug content, *in vitro* floating behavior, and *in vitro* drug release. The % yield of formulations (FM1 to FM9) was found to be in the range of 79.51±3.71 to 93.48±0.94 %. Percentage drug content of floating microspheres formulations (FM1 to FM9) was found in the range of 77.25±0.36 to 86.14±2.04 %. *In vitro* buoyancy percentage of the microspheres was found to be 97.5±1.53 %. At pH 1.2, the best formulation FM4 showed maximum drug release (99.26±1.14 %) at the end of 12 hr. The SEM photographs of formulation FM4 showed that the fabricated microspheres were spherical with a smooth surface and exhibited a range of sizes within each batch. The *in vivo* evaluation for the determination of pharmacokinetic parameters was performed in albino rats. Higher plasma concentration was maintained throughout the study period from the floating microspheres of famotidine. The enhanced bioavailability and elimination half-life observed in the present study may be due to the floating nature of the dosage form. The results suggested that calcium silicate is a useful carrier for the development of floating and sustained release preparations.

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Employing design of experiment approach in the optimization of a generic drug product formula in reaction with the similarity index of dissolution profile for the drug product Innovator

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Design of experiment (DOE) concept was conducted thoroughly during the optimization of drug formula (using half factorial 2^3 design). An investigation matrix of active substances including *Paracetamol, Phseudoephdrine* and *Pholcodine* with a concentration of 500mg/Cap, 30 mg/cap and 5 mg/cap respectively was mixed with three excipients which affect of dissolution profile of the drug. Factors of this experiment comprises different concentrations specified for three excepient coded as A, B & C, these concentration were changed systematically to determine the optimum concentration for each excipient to define the optimum dissolution profile matches the innovator's drug product profile.

The dissolution test is preformed according to matrix design between different pH media 2, 4.5, 6.8 and different time intervals 10, 20, 30 minutes, then the dissolved amount of each active substances are calculated in reference to the predefined matrix design. Innovator dissolution is the reference result which is compared with experiments response. Accordingly, using design of experiment approach provides the researcher with the ability study the effect of each excipient concentration and their interactions.

The most similar dissolution profile of generic drug product to the innovator product concluded the excipients ratios in the generic drug formula as A, B and C are 16.3mg/cap, 2.8 mg/cap and 5.6mg/Cap respectively.

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