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Formulation and evaluation of Silymarin floating microspheres

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Introduction: Silymarin has a short half life (4-6 hours) and hence requires frequent administration. It also undergoes degradation in the intestinal pH. These shortcomings can be overcome by formulating the drug as a novel drug delivery system, viz. gastroretentive drug delivery system. This study aims to develop and evaluate silymarin floating microspheres prepared with polymers like hydroxypropylmethyl cellulose E50 LV and ethyl cellulose.

Experimental: Compatibility of the drug and polymers was assessed by Fourier transform infrared spectroscopy. Differential scanning calorimetry studies were also conducted. Floating microspheres of silymarin were prepared by solvent evaporation technique by using polymers like hydroxypropylmethyl cellulose E50 LV and ethyl cellulose. Various evaluation parameters were assessed, viz. surface morphology by scanning electron microscopy, frequency distribution analysis by optical microscopy, percentage yield, drug entrapment and *in vitro* drug release were performed as per the procedures mentioned in the official monographs (Indian Pharmacopoeia & USP). The *in vitro* release data was fitted into various kinetic models, viz. zero order, first order, Higuchi, and Korsmeyer-Peppas model. The time taken for the matrix tablets to start floating (floating lag time) and the duration of floating (buoyancy) were also assessed. In the present study, six formulations were formulated by varying the proportion of ethyl cellulose (1 g to 3.5 g) and keeping the proportion of hydroxypropylmethyl cellulose uniform (700 mg).

Results and Discussion: Fourier transform infrared spectroscopy showed no interaction between the drug and polymers. Silymarin floating microspheres were spherical in nature, which was confirmed by scanning electron microscopy. Silymarin floating microspheres with normal frequency distribution were obtained. A maximum of 89.60% drug entrapment efficiency was also obtained. The *in vitro* drug release study of silymarin floating microspheres showed controlled release which depended on the polymer concentration. The co-efficient of determination indicated that the release data were best fitted with zero order kinetics. Higuchi equation explained the diffusion controlled release mechanism. The diffusion exponent 'n' values of Korsmeyer-Peppas model was found to be non-fickian. The differential scanning calorimetry studies showed that there was a decrease in the crystallinity of silymarin.

Conclusion: All the nine formulations remained buoyant and showed drug release up to 12 hours. Surface smoothness and mean particle size of the silymarin microspheres was increased by increasing the polymer concentration. Entrapment efficiency increased with increase in the polymer concentration. The study also indicated that the amount of drug released decreased with increase in the polymer concentration. The *in vitro* drug release study of silymarin floating microspheres showed prolonged and controlled release of the drug.

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