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Formulation and *In vitro* Evaluation of Floating Microspheres of Misoprostol

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ABSTRACT

Misoprostol is a synthetic prostaglandin PGE1 analogue, which has proved to be an effective anti-secretory agent for oral use. The major indications of Misoprostol are in the prevention and treatment of NSAID-induced gastric and duodenal ulcers. Its half-life is 20-40 minutes. More than one third of patients with ulcers are resistant to H_2 antagonists. So, these patients can be healed on Misoprostol. The objective of the present study was to formulate gastroretentive floating drug delivery system of an antiulcer drug Misoprostol. Floating microspheres of Misoprostol were prepared by an emulsification solvent evaporation technique using hydroxy propyl methyl-cellulose (HPMC K 100M) and ethyl cellulose. The percentage yield and drug entrapment efficiencies of these floating microspheres were within the range between: 70 ± 2.8 to 98 ± 2.9 % and 39.27 to 82.39 %, respectively. The determined mean particle size for all the microspheres were 250 ± 7.28 to 400 ± 2.32 µm. The flowability of these microspheres was found good. A high performance liquid chromatography (HPLC) method with ultra-violet (UV) detection was selected for the method of analysis. The drug release was found to delay for 12 hours with the increasing drug to polymer ratio. The drug release kinetics followed Korsemeyer-Peppas and Higuchi model with anomalous (non-Fickian) diffusion mechanism for the drug release. The FTIR and DSC studies showed that there was an absence of chemical interaction between the drug and the excipients. The *in vitro* drug release from Misoprostol floating microspheres showed the drug release was dependent on the drug to polymer ratio. The drug release was found delayed with the increasing drug to polymer ratio.

KEYWORDS: Floating microspheres; emulsion solvent evaporation method; Misoprostol.