

Design and *in vivo* Evaluation of Gastro-retentive Floating Capsules of Amlodipine Besylate in Healthy Human Volunteers

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ABSTRACT

The aim of this study was to explore the application of Gelucire 43/01 for the design of sustained release gastro retentive drug delivery system of Amlodipine besylate. Gelucire 43/01 has been used in floating sustained release formulations to prolong gastric residence time and increase its bioavailability. Gelucire 43/01 in combination with HPMC and Polyox was used as a release retarding polymer. HPMC of various viscosity grades HPMC K4M, HPMC K15M and HPMC K100M in combination of Gelucire were tested to obtain optimal total floating time as well as controlled drug release for prolonged period. Melt granulation technique has been used to prepare gastro retentive Amlodipine besylate formulations. All the formulations were evaluated *in vitro* for their floating ability and drug release. The floating times of all tablet

formulations were greater than 12h. HPMC K4M in combination with Gelucire as polymeric matrix enhanced the drug release due to addition of hydrophilic polymer facilitated the swelling and erosion of the tablets. Incorporation of low viscosity polymer HPMC K100 M resulted in optimal floating as well as drug release for longer time. *In vivo* studies of optimized formulation show floating ability for 6 h in stomach. The results indicate that Gelucire 43/01 in combination with dissolution enhancers HPMC increase the permeability of the wax matrix, which provides improved dissolution thereby bioavailability of Amlodipine besylate and can be considered as a carrier for the development of sustained release floating drug delivery systems.

KEYWORDS: Amlodipine; Floating delivery; Radiographic studies; Gelucire 43/01; Bioavailability; HPMC.