

Formulation and Evaluation of Sustained Release Floating Tablets of an Antihypertensive Diltiazem

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ABSTRACT

The aim of the present study was to develop and evaluate sustained release floating tablets of Diltiazem hydrochloride, an antihypertensive agent. The sustained release floating tablets were prepared by direct compression method and formulated using different polymer combinations, formulations such as F1 to F9. Natural polymer Sodium alginate and synthetic polymer HPMC K4M were used. Developed formulations were evaluated for the pre compression parameters i.e., drug- excipients compatibility by FTIR, bulk density, compressibility, and angle of repose etc. Post compression parameters i.e. weight variation; full factorial design was applied to optimize the developed formulation. SA and HPMC K4M were selected as independent variable at three different concentrations. The *in-vitro* drug release study revealed that formulation F8 combination of both synthetic (HPMC) and natural polymers (sodium alginate) was the most successful formulation of the study, all tablets but

one exhibited gradual and near complete sustained release for diltiazem HCl (90-100%) that extended the drug release up to 8 hours, with satisfactory drug release in the initial hours, and the total release pattern was close to the theoretical release profile. Model equations of zero and first order, Higuchi, Hixson-Crowell and Peppas, intended to elucidate the drug release mechanism, and were fitted to the release data. Mathematical modelling of *in-vitro* dissolution data indicated the best-fit release kinetics was achieved with Higuchi model with r values of 0.994 in its semi log plot. The 'n' value in Higuchi model was >0.89 which indicated, Super Case-II transport of drug from polymer sustained, i.e., diffusion with relaxation of polymeric chain. In conclusion, the results indicated that the prepared sustained-release tablets of Diltiazem hydrochloride could perform therapeutically better than conventional tablets with improved efficacy and better patient compliance.

KEYWORDS: Diltiazem; floating tablets; Sustained-release; Sodium alginate; HPMC; Drug release.