ABSTRACT

Carvedilol is used for hypertension, angina pectoris and in symptomatic heart failure. It has only a short half life of 2 h and oral bioavailability of 25%. Therefore, the present investigation is concerned with the development of the buco-mucoadhesive films to increase the bioavailability of the drug and its half life. Various formulations of dose 12.50 mg were developed by using release rate controlling film forming polymers like Eudragit RL-100, Polyvinyl pyrrolidone, Hydroxypropyl methylcellulose, Sodium Carboxymethyl cellulose and Carbopol 934P in various combinations by solvent casting technique using propylene glycol as plasticizer with and without penetration enhancers like Dimethyl sulfoxide, Tween 60 and castor oil. For unidirectional release, ethyl cellulose as backing layer was used at 10%w/v level in ethanol along with propylene glycol at 5%w/v level as a plasticizer. The most satisfactory formulation had retained on buccal cavity for maximum duration of 10h in the in- vitro studies and released the drug for a prolong period of more than 12 hours during dissolution studies. Dimethylsolfoxide was chosen as the best penetration enhancer as it enhanced the drug permeation by 15% during ex vivo studies. The most satisfactory formulation followed zero order kinetics while the drug release mechanism was found to be anomalous diffusion which was confirmed by Scanning Electron Microscopy. The most satisfactory formulation was stable during stability studies conducted for two months as per ICH Q1C guidelines as it showed no significant changes ($p < 0.05$) in the physicochemical parameters, in vitro release pattern and ex vivo diffusion studies.

Key words: Carvedilol, Buccal drug delivery system, Buccal films, penetration enhancers, stability study.