

“Preparation and *in-vitro* characterization of sustained release Ranolazine-HCl swellable microspheres”

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Abstract

The objective of this study was to prepare and characterize swellable microspheres of Ranolazine giving sustained release for chronic stable angina. Swellable microspheres were prepared by spray drying method using HPMC (K15 and K100) and carbopol 934P as polymers to achieve sustained drug release. Effect of HPMC concentration, drug: polymer ratio and carbopol concentration on physical properties of microspheres were investigated. Optimization of different process parameters of the spray dryer was performed. The optimization of microspheres was done based on the entrapment efficiency & release rate. Microspheres were characterized in terms of production yield, drug content, entrapment efficiency, particle size, SEM and dissolution studies. Formulation containing 300 mg Carbopol 934P and 700 mg HPMC K15 was found to be optimum formulation. The % yield, % entrapment efficiency, % drug content, swelling index, *in-vitro* drug release (in 10 hrs) and particle size were found to be 32.11%, 84.83%, 89.73%, 1.62, 90.7% and 20.41 μm respectively gave the best results. Optimized formulation followed Hixon Crowell, Korsmeyer- Peppas and zero order models, which indicates that the drug release

followed erosion, swelling and sustained release mechanism. Stability studies at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75 \pm 5\% \text{ RH}$ revealed that there was no significant change in appearance and drug content, after 1 month. So, prepared formulation can be considered as stable formulation. Hence, it can be concluded that the developed swellable microspheres can be effectively used for oral administration in case of chronic stable angina.

Keywords: Swellable microspheres, chronic stable angina, spray drying, sustained release.