

Formulation And Evaluation Of Double Layered Microspheres Of Antihypertensive Drugs

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Abstract:

In the treatment of hypertension, combination therapy has been found to be better than monotherapy as combining the drugs results in convenient dosing format, lowering of the dose, reduction in the side effects, increase in therapeutic efficiency and enhanced patient compliance. Combination of amlodipine besylate/losartan potassium has shown to significantly lower blood pressure as compared with monotherapy. In the present study, an attempt was made to develop multiparticulate drug delivery system in the form of double layered microspheres where after initial burst of amlodipine besylate from the immediate release eudragit E100 layer giving rapid onset of action, the sustained release core of losartan potassium would be retained in the gastro intestinal tract releasing the drug over a prolonged period. The core microspheres consisting of losartan potassium, and polymers sodium alginate and chitosan, were prepared by ionotropic gelation method. These microspheres were coated with Eudragit E100 and drug amlodipine besylate having solvent evaporation method. The microspheres were evaluated for particle size, drug loading efficiency, mucoadhesion, and drug release study. The optimized chitosan-alginate core microspheres formulation had particle size of 660 μm , drug loading efficiency of 93.8%, mucoadhesion of 70 %, and drug release of 95% in 23 hours. The optimized double layered microspheres had particle size of 604 μm and drug loading efficiency of 72.23%. The drug release study revealed that 95.72% amlodipine besylate was released in 2 hours and 95% losartan

potassium was released in next 24 hours. Stability studies at $40^0 \pm 2^0$ C and $75 \pm 5\%$ RH for 14 days, of an optimized batch, showed no significant change in drug loading efficiency as well as on drug release behavior. Hence it can be concluded that the developed multiparticulate system may prove to be an effective combination dosage form to treat hypertension for longer period.

Keywords: double layered microspheres, chitosan-alginate microspheres, Ionotropic gelation, solvent evaporation, losartan potassium, amlodipine besylate, immediate release, sustained release, hypertension.