Influence of pluronic F-68 on dissolution and bioavailability characteristics of multiple layer pellets of nifedipine for controlled release delivery

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Abstract

A multiple-layer design of pellets for nifedipine was developed using pluronic F-68 to enhance dissolution rate. The influence of ratios of nifedipine in the inner layer to that in the outer layer, the ratios of pluronic F-68 to nifedipine in the solid dispersion, and the thickness of the control membrane on dissolution characteristics were investigated. With an increasing ratio of pluronic F-68 to nifedipine, the dissolution rate of nifedipine was gradually promoted and the extent of release was enhanced as well. DSC thermograms illustrate the gradual disappearance or broadening of the nifedipine melting peak with the presence of pluronic F-68. The decrease of the nifedipine ratio in the inner layer and the increase of the ratio of pluronic F-68 to nifedipine in the outer layer can enhance the release of nifedipine. With a fixed nifedipine ratio of 1.5 between the inner layer and the outer layer, increasing the ratio of pluronic F-68 to nifedipine in the outer layer significantly increased the initial release rate of nifedipine. By increasing the nifedipine ratio of the inner layer to the outer layer to 1:1, the increase of coating percentage referenced to the total weight decreased the release rate of nifedipine from the inner layer. The pharmacokinetic bioequivalence between the test product (Cardilate, N-6) and Coracten was found with a multiple-dose oral administration of 20 mg in 12 healthy, normal Chinese male volunteers.