Formulation development and evaluation of bilayer matrix tablet of diclofenac potassium and famotidine

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Abstract

The aim of present study is to formulate and evaluate the bilayered tablets containing diclofenac potassium in the sustained release (SR) portion and famotidine in the immediate release (IR) portion in order to produce a single tablet containing two different classes of drugs as widely prescribed by doctors and to have better patient compliance. The sustained release layer of diclofenac potassium was prepared by using mixture of carbopol 934 and HPMC K100M in different proportion and along with other excipients like magnesium stearate, PVP K30 by wet granulation technique. The Immediate release layer of famotidine was prepared by direct compression method. The powders were evaluated for their flow properties and the finished tablets were evaluated for their physical parameters. The drug release study of famotidine and diclofenac potassium were evaluated using USP-XXII paddle type dissolution apparatus. The release rate of famotidine was studied for 45 min using phosphate buffer pH 1.2 as media and that of diclofenac potassium was studied for 2 h in 1.2pH buffer followed by 6 h in pH 6.8 phosphate buffer media. The release rate of famotidine from all the formulations was more than 80% at 45 min. In case of carbopol 934 and HPMC K100M based tablets with the increasing of polymer concentration the release was decreased. Total 9 batches of each drug have been manufactured to optimize and develop a robust and stable formulation. The stability studies of the products also comply with ICH guidelines.

Key words: Bilayer tablet, Diclofenac potassium, Famotidine, Carbopol 934, HPMC K100M , Polyvinyl pyrollidone K-30, Wet granulation, Direct compression.