The Effect of pH and Ionic Strength of the Dissolution Media on the Rate of Drug Release from Matrix Tablets

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Abstract

The gastrointestinal tract (GIT) is a highly specialized region of the body whose primary function involves the process of secretion, digestion, and absorption. Therefore, human GIT is characterized by its complex physiology. Quetiapine is a weakly basic drug of low solubility and high permeability (BCS class II). It shows pH-dependent solubility that may show release problems from sustained release dosage forms at higher pH of small intestine. In this study, quetiapine fumarate (QF) was used as a model drug. Two matrix tablet formulations (F1 and F2) that would attain controlled delivery of QF over 24 h were prepared using different polymeric blends. F1 matrix tablets were prepared using a combination of the low viscosity grade hydroxypropyl methylcellulose (HPMC K100LV) and the high viscosity grade HPMC K4M at a ratio of 2.4:1. F2 matrix tablets were prepared using the high viscosity grade HPMC K4M and the amphiphilic excipient PEGylated glyceryl behenate (Compritol® HD5 ATO). Dissolution testing is a requirement for all solid oral dosage forms. It is used in all phases of development for product release and stability testing. In this study, the effect of pH, buffer capacity, and ionic strength on the solubility and dissolution behavior of QF from controlled release matrix tablets was investigated. Media that simulate the gastric and intestinal fluids and cover the physiological pH, buffer capacity, and ionic strength range of the GIT were used in the solubility and *in vitro* dissolution studies. The dissolution profiles of the two formulations in each dissolution medium were compared, in an attempt to better select a suitable *in vitro* dissolution medium for matrix tablet formulations containing QF.