ABSTRACT

Validation Method of HPLC for Indication Stability Omeprazole in the Capsule Preparation

Krisna Shakti Mahardika

The purpose of this study was to obtain HPLC analysis method that could separate omeprazole from the degradation product. Validation parameters of the method were specificity, selectivity, linearity, accuracy and precision determined according to the United States Pharmacopoeia (USP 40) . A forced degradation by acid, base, and heat was performed on Omeprazole. The results showed that optimum condition of chromatographic separation for these compounds and the degradation products was achieved by using a LiChrospher RP-18 (5 μm) column with mobile phase of acetonitrile phases : phosphate buffer pH 8 (40: 60 v / v). The flow rate was 1.0 ml / min with column temperature of 25° C. The Injection volume was 10μL and the wavelength used was 280 nm. This method met the validation requirements with linearity response of 0.9997, 99.07% accuracy (98.0 - 102.0%, and the standard deviation (RSD) of 1.01%.

Keywords: Omeprazole, Forced Degradation, HPLC, Validation.