Abstract

DEVELOPMENT AND VALIDATION OF HPLC METHOD FOR DISSOLUTION STUDY OF ANDROGRAPHOLIDE FROM TABLET CONTAINING ETHYL ACETATE-96 FRACTION

The development and validation of analytical methods for dissolution testing is an important role to support the development of new drugs. Phytopharmaca has been developed as antimalarial in the form of ethyl acetate-96 fraction tablet. The dissolution of the tablet determines the speed of the drug dissolves in the systemic circulation, it aims to ensure the quality, safety and efficacy of drug products.The selective, specific and rapid of high-performance liquid chromatography (HPLC) method has been developed dan validated for andrographolide dissolution test in ethyl acetate-96 fraction tablet. This method was performed using poroshell column (3.0 x 50 mm i.d., 2.7µm parcticle size) as stationary phase, column temperature was maintained at 30°C, isocratic mobile phase of methanol : water (pH 3.05 with phosporic acid) (50:50 v/v) mobile phase with flow rate of 0.3 ml/menit, injection volume 0,5µl and detected at 228 nm. The test was performed by optimization of method conditions that has also been fully validated in SST, selectivity, linearity, precision, accuracy, robustness and was obtained LOD and LOQ. The results showed that method was selective to separate andrographolide peak from matrix with good resolution, retention time andrographolide was 2.5 minute. The data for calibration plots showed good linear relationship with r = 0,9997 dan Vxo = 1.6 % in HCl, r = 0,9999 dan Vxo = 0.9 % in acetat, r = 0.9996 dan Vxo = 1.9 % in phosphat with the concentration range 10-100 ppm. The limit of detection and quantification were found 0.65365 ppm and 2.17882 ppm in HCl, 1.02159 ppm and 3,40530 ppm in acetat, 0.27116 ppm and 0.90388 ppm in phosphat respectively. The recovery method was found between 99.62% - 101.86% in HCl, 96.62% - 99.81% in acetat, and 95.07% - 101.11% in phosphat. The relative standard deviation method was found between 1.48% in HCl, 1.23% in acetat, 1.15% in phophat. Dissolution tests were carried out in sink conditions, as follows in a multibath (n = 6) dissolution test system Erweka DT 700. The apparatus 2 (paddle apparatus) was used with a stirring speed of 75 rpm in 900 ml of dissolution medium (pH 1.2 HCl, pH 4.5 acetate, pH 6.8 phosphate with SLS 0.5%) thermostated at 37.0 ± 0.5°C.

Keywords : Dissolution, Ethyl acetate-96 fraction tablet, HPLC, Method validation, Andrographolide