Analytical Method Development and Validation for Quantification of Ceftiofur Hydrochloride in Veterinary Oily Suspension Using HPLC Coupled with UV Detector

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Abstract

Ceftiofur hydrochloride is a third-generation veterinary cephalosporin antibiotic with a broad spectrum. The aim of the study was to develop and to validate a new rapid and simple liquid chromatographic method for routine analysis of Ceftiofur HCl as veterinary product using high performance liquid chromatography (HPLC). The HPLC analysis was performed on the phenomix C_{18}, 15cm column with a diameter of 4.5 mm and a particle size of 5 µm, with a mobile phase containing a mixture of acetonitrile and phosphate buffer, adjusted to pH 6 with orthophosphoric acid 85%, in the ratio of 25:75% (v/v), at the flow rate of 1.0 mL/min. The UV detection was performed at the wavelength (λmax) of 292 nm, and the retention time of Ceftiofur HCl was around 3.4 min. analytical method validation was done in accordance to ICH guidelines. The method was linear over the range of 0.01 – 0.16mg/ml and found to be specific and accurate with the mean recovery of 100.1 % -101.3%. The values of LOD and LOQ were found to be 0.003 and 0.01 mg/mL respectively. The test of repeatability for standard and sample solutions showed that the method is precise within the acceptable limits as the RSD % was found to be less than 2%. As well the developed method showed

excellent linearity, accuracy, precision, specificity, robustness, LOD and LLOQ results within the acceptance criteria.