HPLC Method for Determination of Cefuroxime Axetil in Pharmaceutical Preparations

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Cefuroxime, (6R, 7R)-3-(carbamoyloxymethyl)-7-[[2Z]-2-(furan-2-yl)-2-methoxyiminoacetyl] amino]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, is a second-generation cephalosporin used against different kinds of bacterial infections. Cefuroxime axetil (CEFA) is its 1-acetyl oxyethyl ester. After oral administration, CEFA is absorbed from the gastrointestinal tract and rapidly hydrolyzed by nonspecific esterases in the intestinal mucosa and blood to CEF, which is subsequently distributed throughout the extracellular fluids. Following oral administration of CEFA tablets, maximum CEF concentration in plasma occurs at 1-4 hours. The elimination half-life is 1-2 hours [1, 2].

Cefuroxime axetil and etodolac (internal standard) reference substances were kindly supplied by Novagenix Pharmaceutical Industry (Ankara, Turkey). Chromatographic analysis was carried out on an Agilent 1200 series HPLC system, consisting of a degasser, quaternary pump, autosampler, and variable wavelength UV detector units. The reversed-phase ACE C18 analytical column (250 mm x 4.6 mm i.D., 5 μm) was used in chromatographic separation, and the mobile phase consisted of acetonitrile-water (80:20, v/v; with 0.1% acetic acid). The flow rate was 1 mL/min, wavelength was 280 nm, and the injection volume was 10 μL. Stock solutions of cefuroxime axetil and IS were prepared in acetonitrile (100 μg/mL). Calibration standards in the concentration range of 0.3, 0.5, 1, 3, 6, and 12 μg/mL were prepared in the appropriate volumetric flasks using internal standard solution a fixed concentration of 3 μg/mL. All standards samples were filtered through a 0.45 μm filter prior injection. A calibration curve was obtained using the cefuroxime axetil/IS peak area ratios for HPLC. The linear regression equations obtained by the least square regression method was y=0.4455x-0.0036 (y representing the peak area ratio of cefuroxime axetil to IS, x representing the concentration of cefuroxime axetil) for the HPLC. The limits of detection (LOD) and limits of quantification (LOQ) were established by decreasing analyte amounts to S/N of 3:1 and 10:1, respectively. The LOD and LOQ were 0.1 and 0.3 μg/mL, respectively.

A simple, rapid, very accurate and precise HPLC method was developed for the determination of Cefuroxime axetil in pure form and in pharmaceutical preparations. The analytical conditions and solvent system developed provided a good separation for cefuroxime axetil within a short analysis time. The method was validated and demonstrated a wide linear dynamic range, a good precision and accuracy and specificity compared to the previously reported HPLC methods. Thus, the method can be proposed for routine analysis laboratories and for quality control.

KEYWORDS: Cefuroxime axetil, HPLC, validation

REFERENCES: