Analytical Method Development and Validation for Simultaneous Estimation of Cefixime and Azithromycin in Bulk and Their Combined Dosage Form

Submitted By

Rokad Jenisha Rameshbhai

Supervised By

Mrs. Pinkal H. Patel

M. Pharm.

Assistant Professor, Dept. of Pharmaceutical Quality Assurance

Baroda College of Pharmacy

Limda, Ta. Waghodia, Dist. Vadodara 391760

ABSTRACT

A simple, accurate and precise UV Spectrophotometric methods and RP-HPLC method was developed and validated for simultaneous estimation of Cefixime and Azithromycin in bulk and tablet dosage form. Two UV spectrophotometric methods were developed. In Q-absorption ratio method determination was carried out at 218 nm λmax of Azithromycin and 225 nm an Iso-bestic point of both the drug. The linearity range lies between 20-40 µg/ml for Cefixime and 50-100 µg/ml for Aithromycin at their respective wavelengths. Both the drugs were found in good agreement with the label claimed in the marketed formulation. In the tablets both the drugs were estimated as 100.2% and 97.84% Cefixime and Azithromycin respectively. While in another Absorption correction method Cefixime was estimated at 288 nm, at this wavelength Azithromycin show zero absorbance and no interference. For estimation of Azithromycin corrected absorbance was calculated at 220 nm due to the interference of Cefixime at this wavelength. Calibration curves were linear with correlation coefficient between 0.999 over the concentration range of 20-40 µg/ml and 50-100 µg/ml for

Cefixime and Azithromycin respectively. In the tablets both the drug were estimated as 100% and 99.96%, Cefixime and Azithromycin respectively. The RP-HPLC method for simultaneous estimation of Cefixime and Azithromycin. The separation was achieved on a Phenomenex luna ODS C_{18} (250mm X 4.6 mm i.d., 5 µm particle size) with an isocratic mixture of acetonitrile: methanol: 1N NaOH: 80mM phosphate buffer pH 5.6 adjusted with glacial ortho-phosphoric acid in the ratio of 30:15:2.5:52.5 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection was kept at 215 nm. The retention time Cefixim and Azithromycin was 2.41±0.1min and 3.977±0.1min, respectively. The linearity of a simple, accurate, precise RP-HPLC method was developed and validated for simultaneous estimation of Cefixime and Azithromycin in bulk and tablet dosage form. The proposed method was investigated in the range of 20-80 µg/ml and 50-200 µg/ml for Cefixime and Azithromycin, respectively. Correlation coefficient was 0.9995 and 0.999 for Cefixime and Azithromycin, respectively. The limit of detection was 0.432 µg/ml and 0.769 µg/ml for Cefixime and Azithromycin, respectively and the limit of quantification was 1.296 µg/ml and 2.307 µg/ml for Cefixime and Azithromycin, respectively.

Keywords: Cefixime, Azithromycine, UV Spectroscopic method, Absorption correction method,Q-Abasorption ratio method and RP-HPLC