

ABSTRACT

Azithromycin is an anti-infective, nitrogen containing macrolide antibiotic. It is used for upper and lower respiratory tract infections, pharyngitis/ tonsillitis, otitis media, skin and soft tissue infections. In USP 24 (United States Pharmacopeia 2000), HPLC method for Azithromycin determination is developed by using Amperometric Electrochemical detector. In present work UV-Visible spectrophotometric detector is used which made the method cheaper as compared to the method mentioned in literature. USP Azithromycin RS (Reference Standard) was obtained from UM Medicinal Laboratory (Pvt) Ltd. Karachi. The HPLC Assay of Azithromycin was obtained from UM Medicinal Laboratory, Karachi. Two Azithromycin samples were obtained from StandPharm Pharmaceuticals, Lahore (with the trade name Resque) and Square Pharmaceuticals, Bangladesh (with the trade name Zimax).

The parameters studied are (1) Buffers of different pH, (2) Mobile phase composition, (3) Wavelength, (4) Column temperature, (5) Flow rate, (6) Concentration of reference standard. The maximum detector response was obtained under following chromatographic conditions **Column:** Kromasil 100 C18, (Octadecyl Silane, ODS, chemically bonded to porous silica) **Mobile phase:** Buffer/Acetonitrile/ Methanol (37:35:02), **Column Temperature:** 60 °C, **Flow Rate:** 1.0 cm³/ min, **Pressure:** 9.0-9.8 M.Pa., **Injection Volume:** 20 μL, **Wavelength:** 230nm, **Run Time:** 5 min. Azithromycin RS gave good peak response in concentration of 250 μg/cm³, 300 μg/cm³, 400 μg/cm³, 500 μg/cm³, 600 μg/cm³ and 700 μg/cm³.

According to USP, for five replicate injections RSD (Relative Standard Deviation) should be less than 2.0 %. The minimum RSD was shown by the concentration of 250 μg/cm³. (RSD, 0.51%). That is why the solutions of azithromycin assay and samples were also prepared in the same concentration. Linearity of Peak response was also observed in Azithromycin RS. Retention time for Azithromycin was found to be 2.65 minutes. The HPLC assay of Azithromycin, is found to be 97.36% and two Azithromycin samples, Resque and Zimax, are found to be 89.27% and 91.12% respectively. All parameters studied by HPLC are in accordance with the International Protocols of United States Pharmacopeia. The method developed for the determination of Azithromycin appears to be more valuable as it is cheaper than that mentioned in literature. Moreover, this method exhibits good linearity, accuracy and precision.