

Development of a simple RP-HPLC-UV method for determination of azithromycin in pharmaceutical dosage forms as an alternative to the USP method

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Background and Aims: The present study was designed to develop a simple, validated liquid chromatographic method for the analysis of azithromycin in pharmaceutical dosage forms using ultraviolet detector.

Methods: The HPLC system with column oven and UV detector was employed. The chromatographic separation was performed on a C18 column, 5 μ m, 250 mm \times 4.6mm. Mobile phase was chosen in order to obtain a good peak in a reasonable retention time and the best selectivity for the drug. Flow rate was 1.5ml/min, Wavelength was set at 215nm and the volume of each injection was 500 μ l.

Results: In order to improve the separation and peak symmetry, the chromatographic variables have been investigated. Phosphate buffer with high pH (8) was used to avoid damaging the column and the low acid stability of azithromycin. The optimum phosphate buffer concentration was found to be 0.02M. An isocratic methanol/buffer mobile phase at the ratio of 90:10 gave the best separation and resolution. Temperature was adjusted at 50 $^{\circ}$ C to facilitate mass exchange with the corresponding decrease of peak broadening and increase in sensibility. At these conditions, azithromycin retention time was roughly 6min. The calibration curve was linear ($Y=3.4\times 10^4+2.0376 \times 10^4X$) over the concentration range of 1-80 μ g/ml with a coefficient of correlation 0.9972. The RSD<5.0% of the replicates showed good precision of the method. %Recovery at each concentration was within the range of 80-120% and shown the accuracy of the procedure. The developed method has the advantage of using UV detector in compare to the USP method in which electrochemical detector has been used. The validated method was successfully applied for determination of a few azithromycin in pharmaceutical dosage forms.

Conclusions: A new specific, validated method for the analysis of azithromycin by using HPLC equipped with UV detection at 215nm has been developed. This method was accurate, precise, specific, sensitive, and linear.

Keywords: Azithromycin; HPLC; UV detection