Validation of a UV spectroscopic method for estimation of azithromycin

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Introduction

The control laboratory of the pharmacy of the Edouard Herriot Hospital carries out physico-chemical and bacteriological analyzes of different drug forms. In this context, an accurate and rapid spectrophotometric method was set for the estimation of azithromycin (AZI) dihydrate in pure and pharmaceutical dosage forms as capsules. (Fig.1) This molecule is a semi-synthetic macrolide antibiotic drug effective against a wide variety of bacteria. It is used for the treatment of a range of adult and paediatric infections, including those of the upper and lower respiratory tract, skin and soft tissues, as well as sexually transmitted diseases.

Experimental method

All spectral measurements were undertaken with Shimadzu UV/VIS double beam spectrophotometer (model 2401 PC) with 1 cm matched quartz cells. First, azithromycin was solubilised in pH 6.8 phosphate + methanol buffer. Then, solutions were dissolved under ultrasound for 5 to 10 min. Finally, the blank cell was realized with water and all solutions were analyzed. The macrolid shows an absorbance peak at 215 nm. The same procedure was followed for three days to study inter-day variations and by three different analysts for inter-analyst studies.

Results and discussion

The method was validated for different parameters like specificity, linearity, accuracy, precision (repeatability, reproducibility, intermediate precision) limit of quantification (LOQ) and limit of detection (LOD).

Specificity
The UV-Spectrum of AZI showed no change in the presence of common excipients (lactose + carmine) used for the formulation. So there is no interference in the measurement of antibiotic

Linearity
The linearity was found in the range of 1.5-3.6 g/L supported by high regression coefficient of 0,990 for 3 days. (Figure 2) Therefore the method can be considered as linear.

Accuracy
The accuracy of the method was checked by determining the percentage recovery values.

$$\%\ recovery = \frac{experimental\ concentration}{theoretical\ concentration}$$

This percentage recovery values is in a confidence interval: 96 % to 100 % which is a correct result.

Limit of quantification and limit of detection
LOD and LOQ are terms used to describe the smallest concentration of a measure and that can be reliably measured by an analytical procedure.

LOD	0.24 g/L
LOQ	0.73 g/L

Figure 1: Structure of AZI ($C_{38}H_{72}N_2O_{12}\ 2H_2O$)

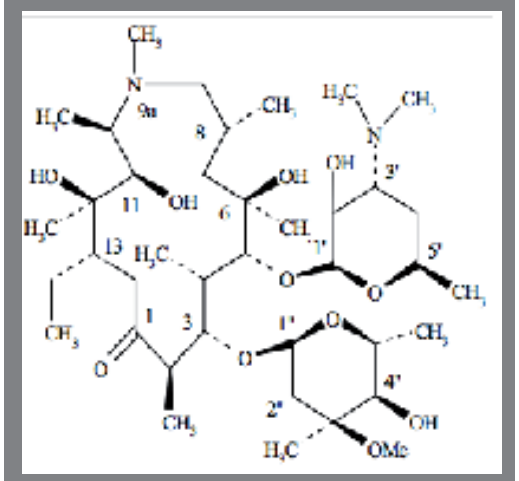
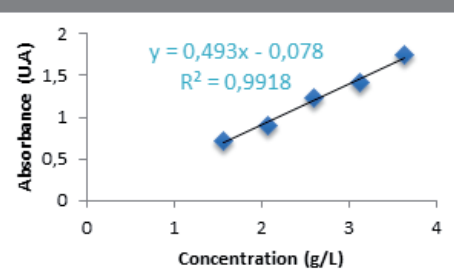


Figure 2: Standard calibration curve of AZI in pH 6.8 phosphate + methanol buffer.



Conclusion

A simple, rapid, accurate and precise method was developed for UV determination of azithromycin. The method was validated. It demonstrated a wide linear range, a good precision, accuracy and specificity. The method is sufficiently sensitive to measure the antibiotic.

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