Azithromycin in pharmaceutical dosage forms

USP method using ALEXYS® LC-EC system

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Introduction

Azithromycin (Azi) is a semi-synthetic macrolide antibiotic chemically related to erythromycin and clarithromycin [1-4]. It is effective against a wide variety of bacteria organisms, such as *Hemophilus influenzae, Streptococcus pneumoniae, Staphylo-coccus aureus,* and many others. Azithromycin is used to treat bacterial infections such as bronchitis, pneumonia, sexually transmitted diseases (STD), and infections of the ears, lungs, skin, and throat.

The official USP method has been applied for analysis of pharmaceutical formulations, using an ALEXYS 100 LC-EC system with a dual flow cell configuration.

Fig. 1. ALEXYS system for Azithromycin.

Method

HPLC	ALEXYS 100 'Azithromycin USP' system (p/n 180.0086)
Flow cell 1	Flexcell™ cell, GC with Hy-REF™
Flow cell 2	VT-03, 3 mm GC sb REF, 50 µm spacer
$V_{Injection}$	50 µL
T_{oven}	35 °C
Flow rate	1 mL/min

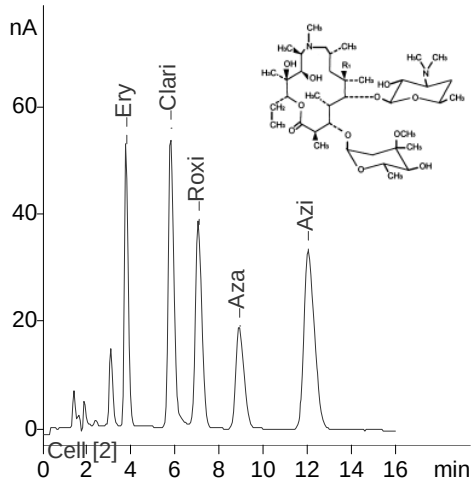

Fig. 2. Analysis of Clarithromycin, Erythromycin, Roxithromycin, Azaerythromycin and Azithromycin.

USP criteria

The USP method has a number of method specifications for selectivity, reproducibility, peak asymmetry, plate number and relative retention time. In Table 1 the criteria of the USP are compared with the specifications of the system.

	USP	Aza	Azi
Retention time (min)	-	8.4	11.6
Rel. retention time	0.7 and 1	0.7	1
Theoretical Plates	> 1000	2725	3020
%RSD area (4.4 µM)	< 2.0%	0.9 %	0.9 %
Resolution	> 2.5		4.2
Asym.	0.9 to 1.5	1.4	1.3

Reproducibility and linearity

The chromatographic resolution is determined by injecting a standard solution of 4.5 µM Aza and 4.4 µM Azi. Resolution of Azi and Aza is better than 4 (Fig. 3). The relative retention time of Aza vs. Azi is 0.7. The repeatability has been studied for 10 replicate injections of 4.4 µM of Azi and Aza. The relative standard deviation in peak areas was < 1% (Fig. 3). Linearity is measured in the concentration range 0.1 – 40 µM Azi and resulted in a correlation coefficient of 0.9992.

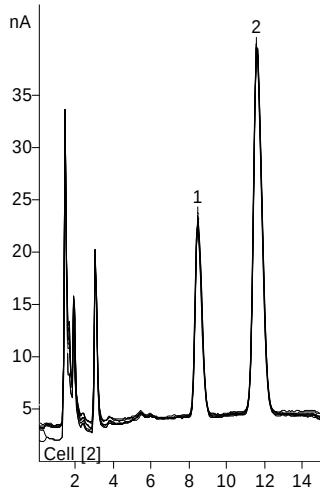

Fig. 3. Overlay of repeatability study of 4.4 µM Aza (1) and 4.4 µM Azi (2).

Conclusion

The official USP method has been applied for analysis of Azithromycin in pharmaceutical formulations. The ALEXYS 100 LC-EC system with a dual flow cell setup shows excellent performance and under the specified LC conditions all USP criteria are met.

References

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