



Certificate of Analysis

Azithromycin USP

Catalog Number: AZ1004
Lot Number: 0906804
CAS Number: 83905-01-5
Molecular Formula: C₃₈H₇₂N₂O₁₂
Molecular Weight: 748.98
Storage: 15°C – 30°C
Date of Manufacture: May 27, 2018
Retest Date: May 26, 2020

Test	Specification	Result
Appearance	Off-white powder	Conforms
Assay (HPLC)	945 – 1030µg/mg	991µg/mg
Identification (FTIR, HPLC)	To match reference standards	Conforms
Solubility	Soluble in ethanol and methylene chloride	Conforms
Specific Rotation	-45° to -49°	-47°
Crystallinity	To meet requirements	Conforms
pH (2mg/ml, 50% MeOH)	9.0 – 11.0	10.1
Moisture	4.0% - 5.0%	4.5%
Residue on Ignition	≤ 0.3%	0.02%
Heavy Metals	≤ 25ppm	< 25ppm
Related Substances (USP40)		
Impurity A	≤ 0.5%	< 0.10%
Impurity B	≤ 1.0%	0.51%
Impurity C	≤ 0.5%	0.13%
Impurity J	≤ 0.3%	0.16%
Impurity E	≤ 0.5%	Not detected
Impurity F	≤ 0.5%	< 0.10%
Impurity G	≤ 0.5%	Not detected
Impurity I	≤ 0.7%	Not detected
Impurity L	≤ 0.5%	Not detected
Impurity M	≤ 0.5%	Not detected
Impurity N	≤ 0.5%	Not detected
Impurity O	≤ 0.5%	0.13%
Impurity P	≤ 0.2%	< 0.10%
Any Other Impurity	≤ 0.2%	< 0.10%
Total Impurities	≤ 3.0%	0.91%
Residual Solvents		
Methylene Chloride	≤ 600ppm	Not detected

For research or further manufacturing. Not for drug, clinical or a food use in humans or animals.



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Acetone	$\leq 5,000\text{ppm}$	475ppm
This lot meets USP 40 requirements.		

Approved by:

Date: September 6, 2018

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