



Specification

Azithromycin USP

Catalog Number:	AZ1004
CAS Number:	83905-01-5
Molecular Formula:	C ₃₈ H ₇₂ N ₂ O ₁₂
Molecular Weight:	748.98
Storage:	15°C – 30°C
Retest Date:	Two years after date of manufacture.

Test	Specification
Appearance	Off-white powder
Assay (HPLC)	945 – 1030µg/mg
Identification (FTIR, HPLC)	To match reference standards
Solubility	Soluble in ethanol and methylene chloride
Specific Rotation	-45° to -49°
Crystallinity	To meet requirements
pH (2mg/ml, 50% MeOH)	9.0 – 11.0
Moisture	4.0% - 5.0%
Residue on Ignition	≤ 0.3%
Heavy Metals	≤ 25ppm
Related Substances (USP40)	
Impurity A	≤ 0.5%
Impurity B	≤ 1.0%
Impurity C	≤ 0.5%
Impurity J	≤ 0.3%
Impurity E	≤ 0.5%
Impurity F	≤ 0.5%
Impurity G	≤ 0.5%
Impurity I	≤ 0.7%
Impurity L	≤ 0.5%
Impurity M	≤ 0.5%
Impurity N	≤ 0.5%
Impurity O	≤ 0.5%
Impurity P	≤ 0.2%
Any Other Impurity	≤ 0.2%
Total Impurities	≤ 3.0%
Residual Solvents	
Methylene Chloride	≤ 600ppm
Acetone	≤ 5,000ppm

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



Gojira Fine Chemicals, LLC

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Approved by:

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