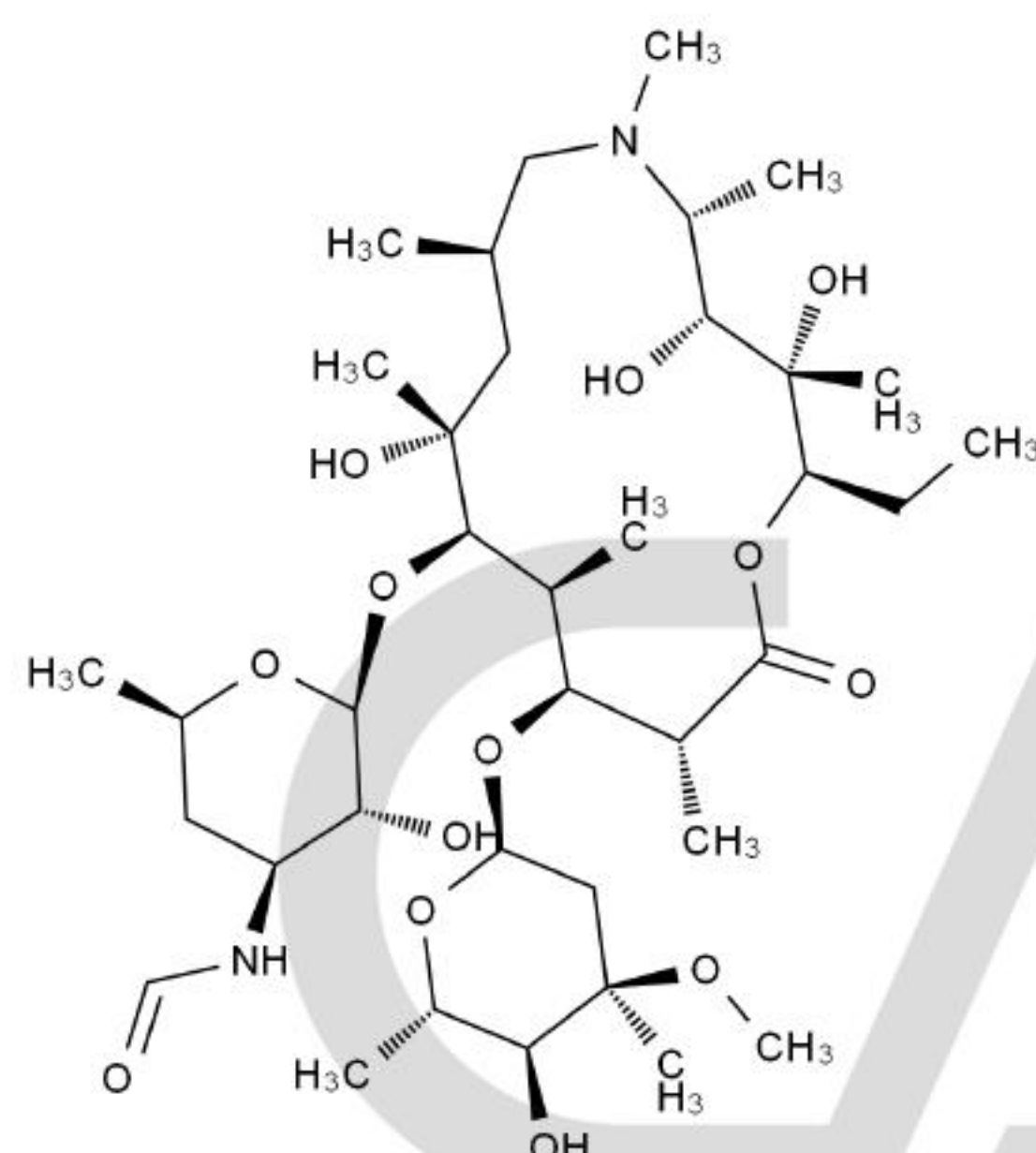


Certificate of Analysis

Reference Material & Standard

Product Name:	Azithromycin EP Impurity M	Catalogue Number:	C4X-100314
Synonyms:	N/A	Lot Number:	0526-RG-0106
CAS Number:	765927-71-7	Expiry Date:	May 20, 2028
Molecular Formula:	C ₃₇ H ₆₈ N ₂ O ₁₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	748.94	Shipping Condition:	Shipping with Ice Packs

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&CNMR&HNMR	Confirmed
Purity	HPLC	99.165%
Water Content	Karl Fischer	2.39%
Residual Solvents	NMR	0.53% acetone
Assay		96.3%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100%-Water Content-Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Reviewed by:

Approved by General Manager:

Date: Dec 26, 2025

Date: Dec 26, 2025

Date: Dec 26, 2025



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