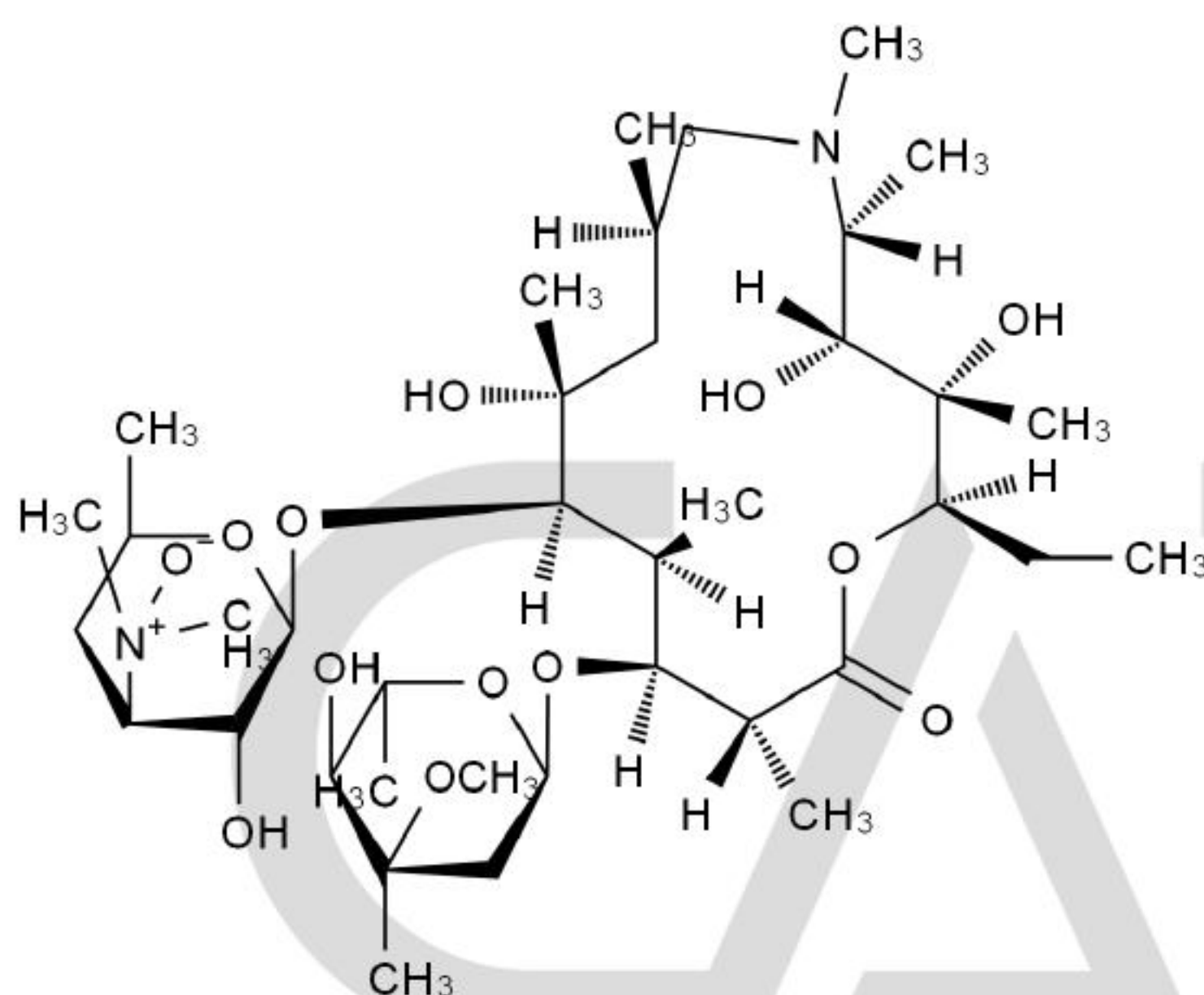


Certificate of Analysis

Reference Material & Standard

Product Name:	Azithromycin EP Impurity L	Catalogue Number:	C4X-100312
Synonyms:	N/A	Lot Number:	1222-RG-0043
CAS Number:	90503-06-3	Expiry Date:	Oct 14, 2028
Molecular Formula:	C ₃₈ H ₇₂ N ₂ O ₁₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	764.98	Shipping Condition:	Shipping with Ice Packs

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&UV&CNMR&HNMR	Confirmed
Purity	HPLC	98.718 %
Water Content	Karl Fischer	3.75%
Residual Solvents	NMR	Not detected in NMR
Assay		95.0%

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:

Nice

Reviewed by:

Koi

Approved by General Manager:

David

Date: Dec 29, 2025

Date: Dec 29, 2025

Date: Dec 29, 2025



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