

Certificate of Analysis

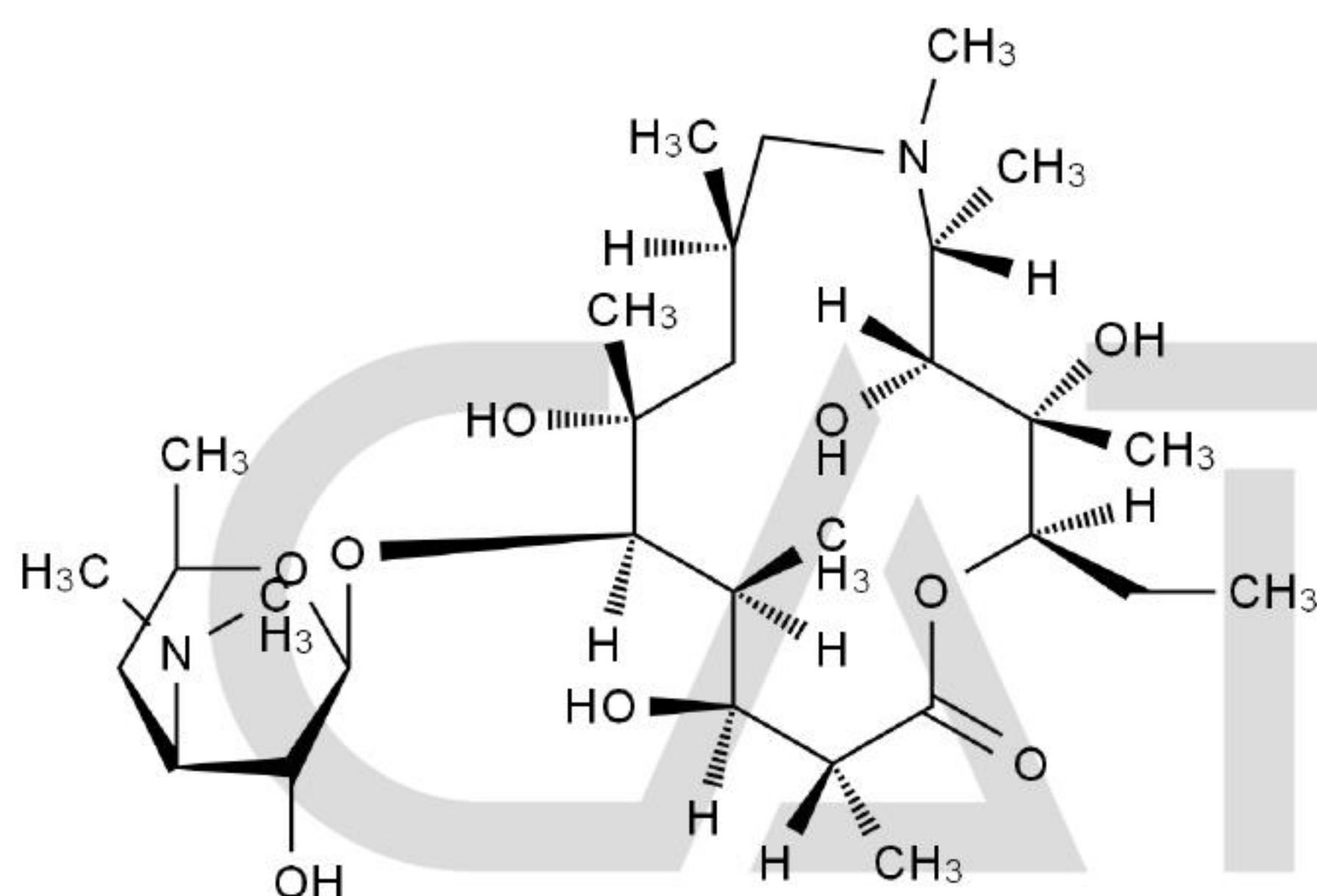
Reference Material & Standard

Product Name:	Azithromycin EP Impurity J	Catalogue Number:	C4X-100315
Synonyms:	Desosaminylazithromycin/Azithromycin CP Impurity J	Lot Number:	0324-RH-0073
CAS Number:	117693-41-1	Expiry Date:	Mar 29, 2030
Molecular Formula:	C ₃₀ H ₅₈ N ₂ O ₉	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	590.79	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.726%
Loss On Drying	TGA	0.7674%
Assay		98.0%

Comment:

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

Assay (%) = (100% - Loss On Drying) * Purity HPLC (%) / 100%

Loss On Drying is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

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Approved by General Manager:

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Date: Mar 30, 2026

Date: Mar 31, 2026

Date: Mar 31, 2026



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