

Certificate of Analysis

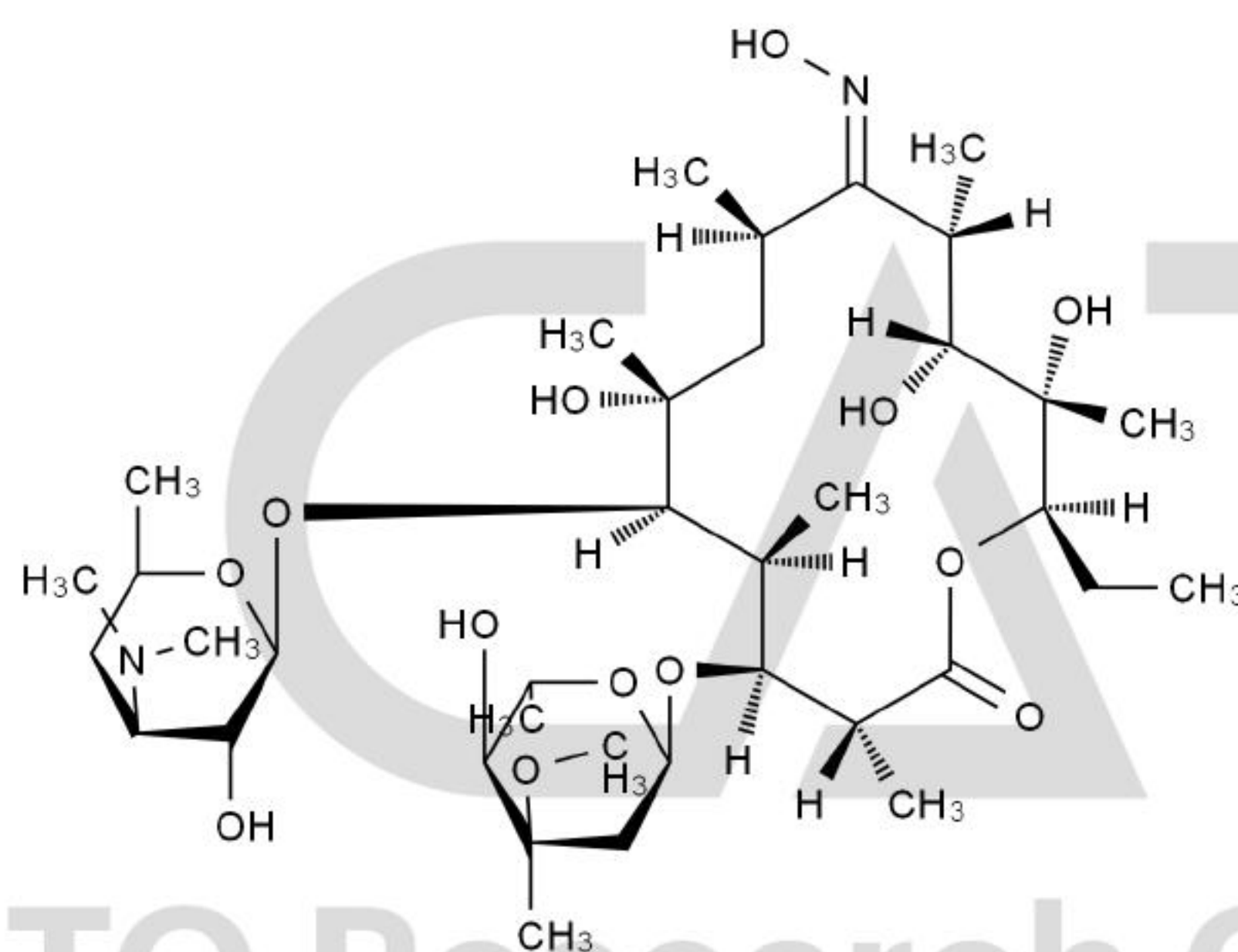
Reference Material & Standard

Product Name:	Clarithromycin EP Impurity J(Roxithromycin EP Impurity C)	Catalogue Number:	C4X-10022
Synonyms:	(9E)-Erythromycin A Oxime/Azithromycin CP Impurity S/Erythromycin A oxime	Lot Number:	1122-RF-0044
CAS Number:	111321-02-9	Expiry Date:	Dec 24, 2027
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

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&CNMR&HNMR	Confirmed
Purity	ELSD	100.0000%
Loss On Drying	TGA	0.815%
Assay		99.2%

Comment:

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

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

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

Signature:

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Date: Dec 01, 2025

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