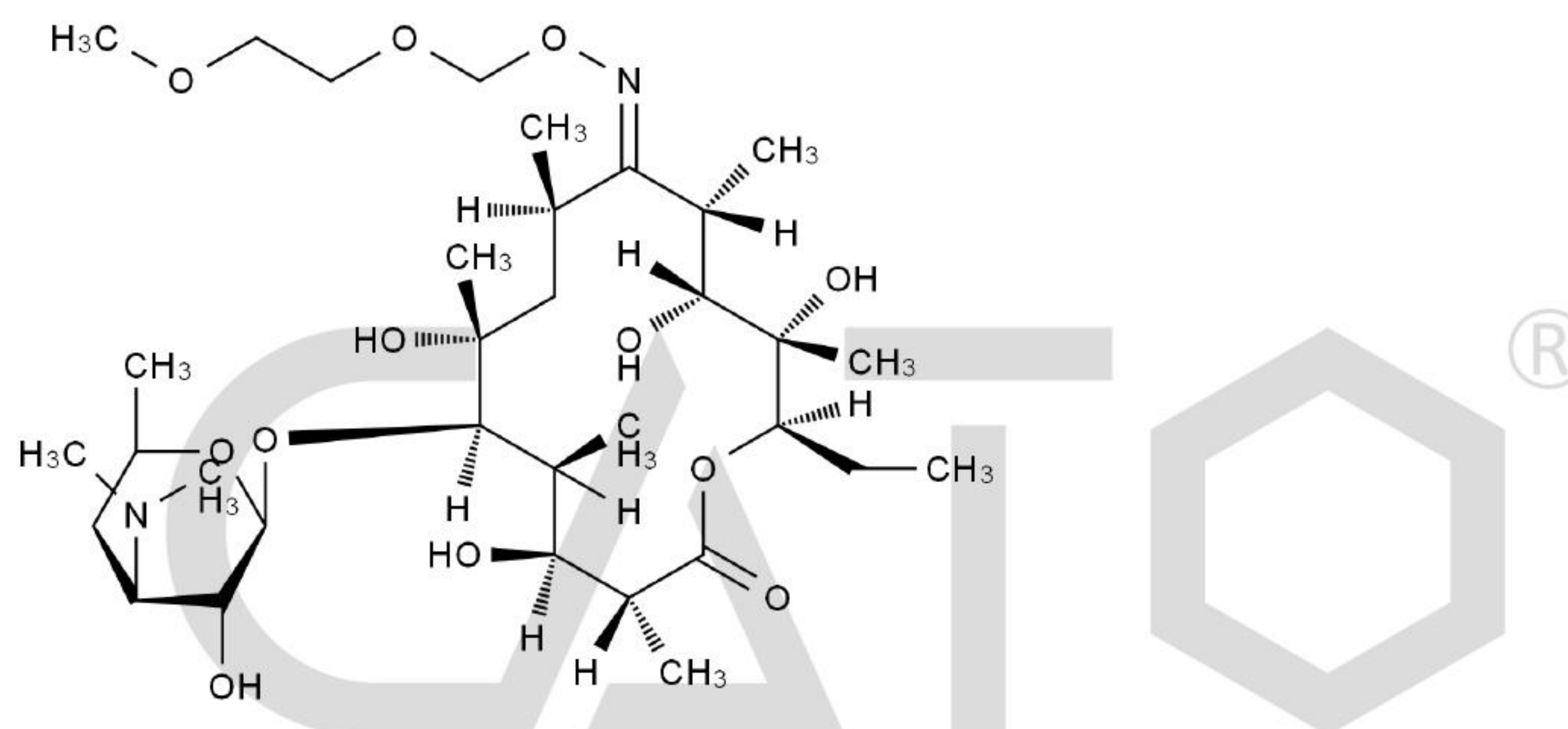


Certificate of Analysis

Reference Material & Standard

Product Name:	Roxithromycin EP Impurity B	Catalogue Number:	C4X-13032
Synonyms:	N/A	Lot Number:	0121-RH-0013
CAS Number:	214902-82-6	Expiry Date:	Nov 12, 2029
Molecular Formula:	C ₃₃ H ₆₂ N ₂ O ₁₂	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	678.85	Shipping Condition:	Shipping with Ice Packs

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	95.0648%
Loss On Drying	TGA	0.533%
Assay		94.6%

Comment:

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

$\text{Assay (\%)} = (100\% - \text{Loss On Drying}) * \text{Purity HPLC (\%)} / 100\%$

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

Signature:

Prepared by:

Reviewed by:

Approved by General Manager:

Date: Jan 21, 2026

Date: Jan 21, 2026

Date: Jan 21, 2026



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