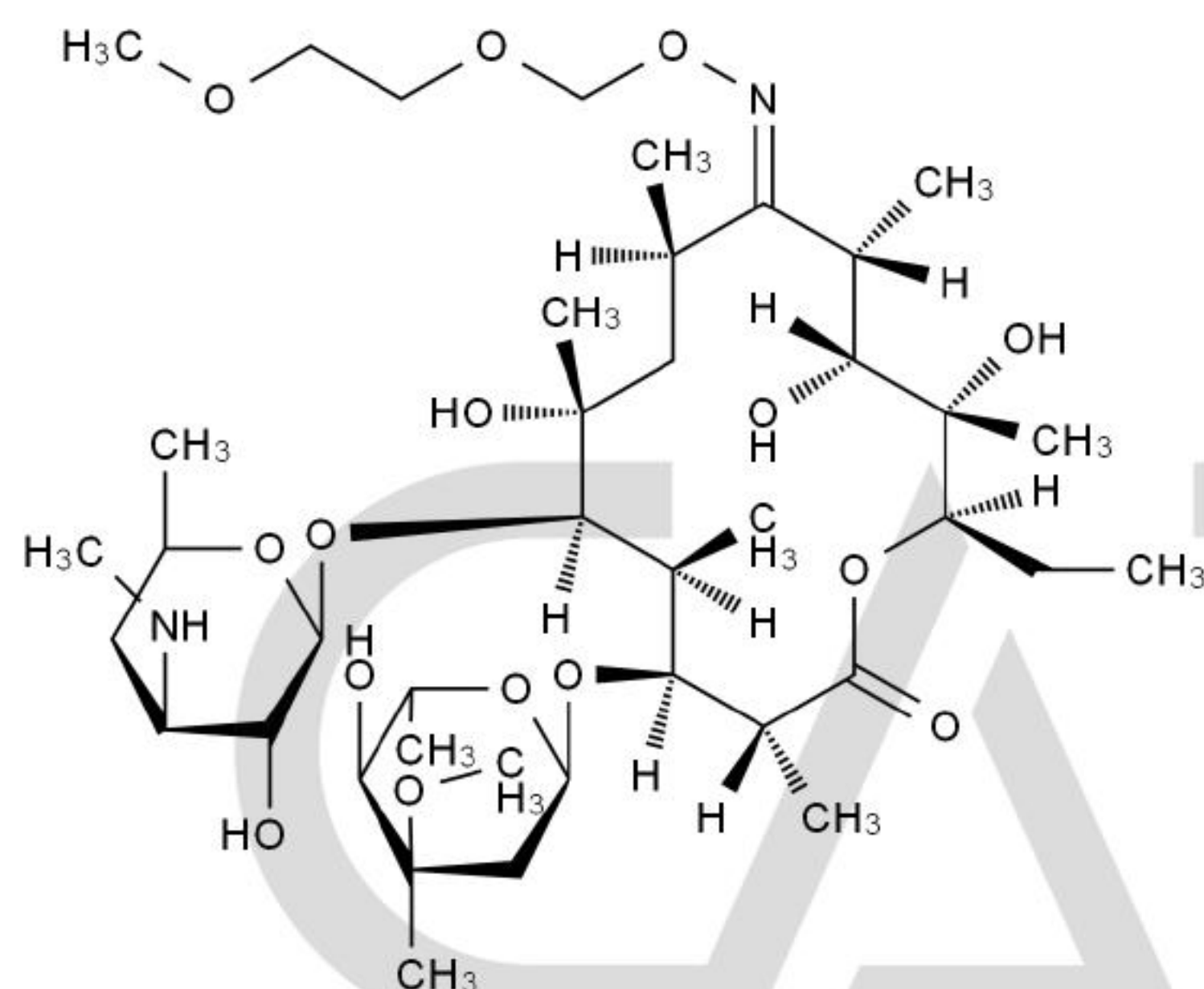


Certificate of Analysis

Reference Material & Standard

Product Name:	Roxithromycin EP Impurity F	Catalogue Number:	C4X-13036
Synonyms:	N/A	Lot Number:	0905-RG-0119
CAS Number:	118267-18-8	Expiry Date:	Mar 26, 2028
Molecular Formula:	C ₄₀ H ₇₄ N ₂ O ₁₅	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	823.02		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	97.973%
Water Content	Karl Fischer	1.04%
Residual Solvents	NMR	Not detected in NMR
Assay		97.0%

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:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Mar 27, 2024

Date: Sep 08, 2025

Date: Sep 08, 2025



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