

Certificate of Analysis

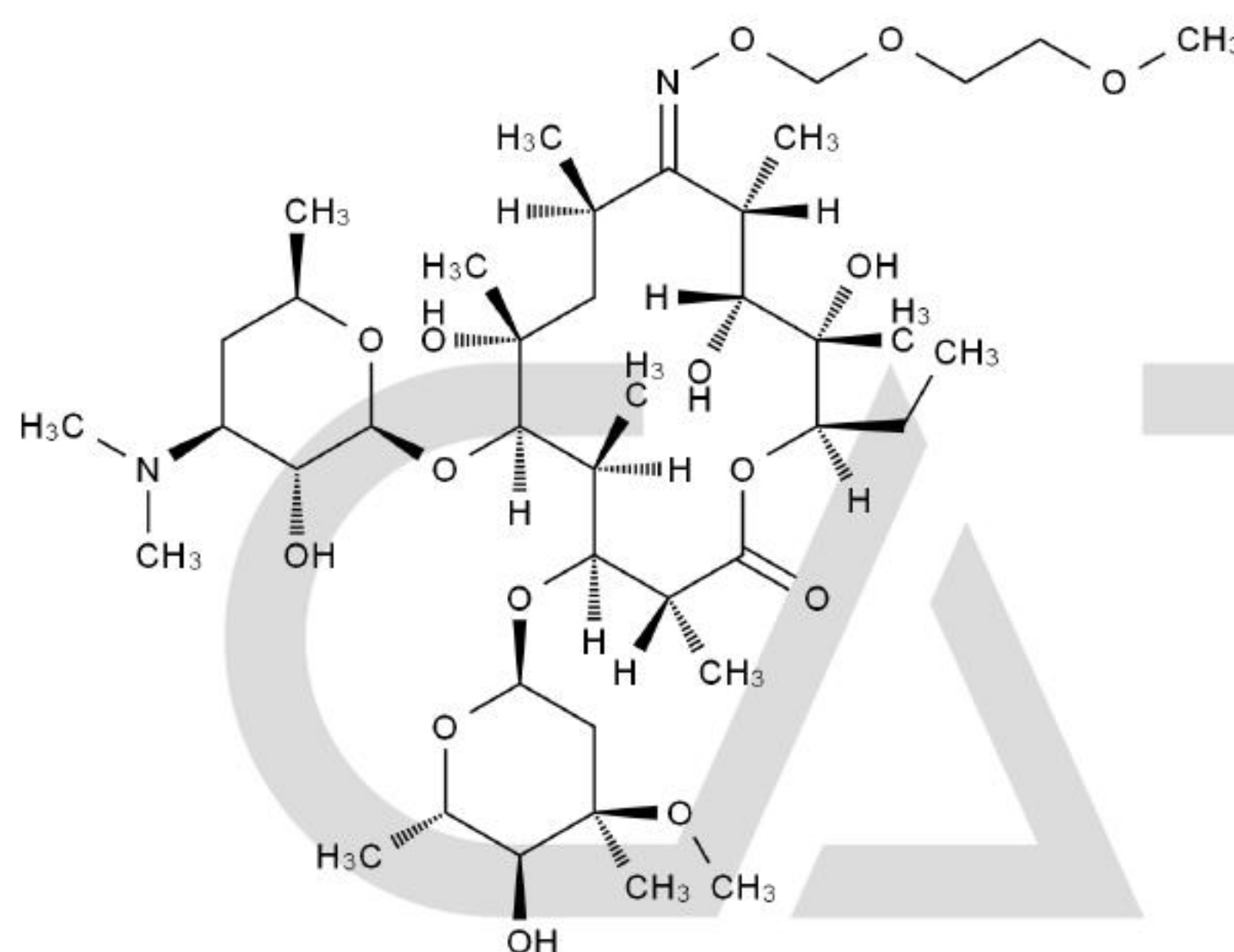
Reference Material & Standard

Product Name:	Roxithromycin EP Impurity D	Catalogue Number:	C4X-13034
Synonyms:	N/A	Lot Number:	0305-RH-0041
CAS Number:	134931-00-3	Expiry Date:	Jan 03, 2030
Molecular Formula:	C ₄₁ H ₇₆ N ₂ O ₁₅	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	837.05	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.7110%
Loss On Drying	TGA	1.611%
Assay		97.1%

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:

Prepared by:

Reviewed by:

Approved by General Manager:

Date: Mar 09, 2026

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