

Certificate of Analysis

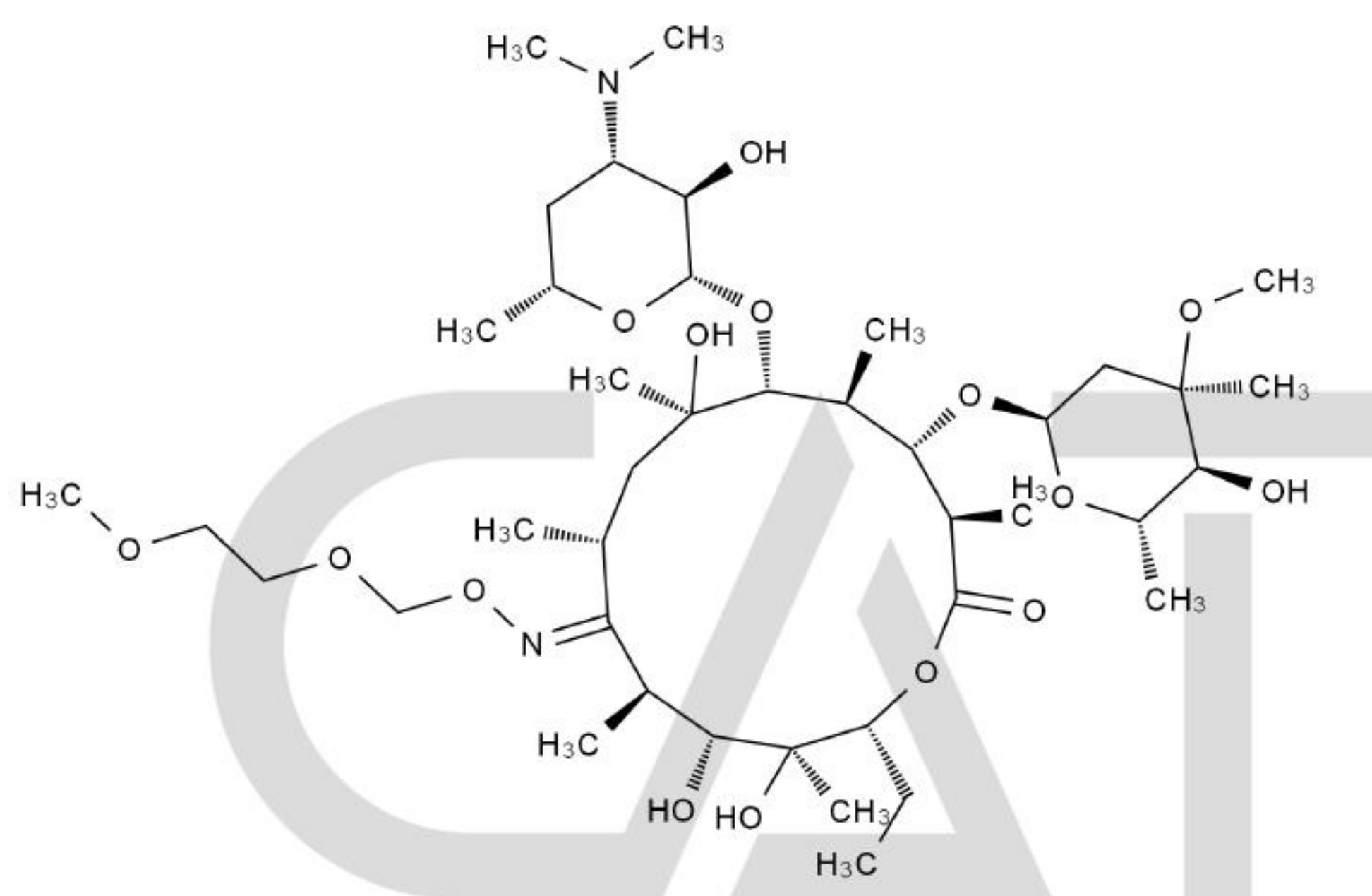
Reference Material & Standard

Product Name:	Roxithromycin	Catalogue Number:	CCAD300403
Synonyms:	N/A	Lot Number:	0702-RH-0037
CAS Number:	80214-83-1	Expiry Date:	Jul 01, 2030
Molecular Formula:	C ₄₁ H ₇₆ N ₂ O ₁₅	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	837.05	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	ELSD	99.432%
Loss on Drying	TGA	1.2464%
Assay		98.2%
Uncertainty		±0.3%

Comment:

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

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

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

2. The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

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Approved by General Manager:

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Date: Jul 02, 2026

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