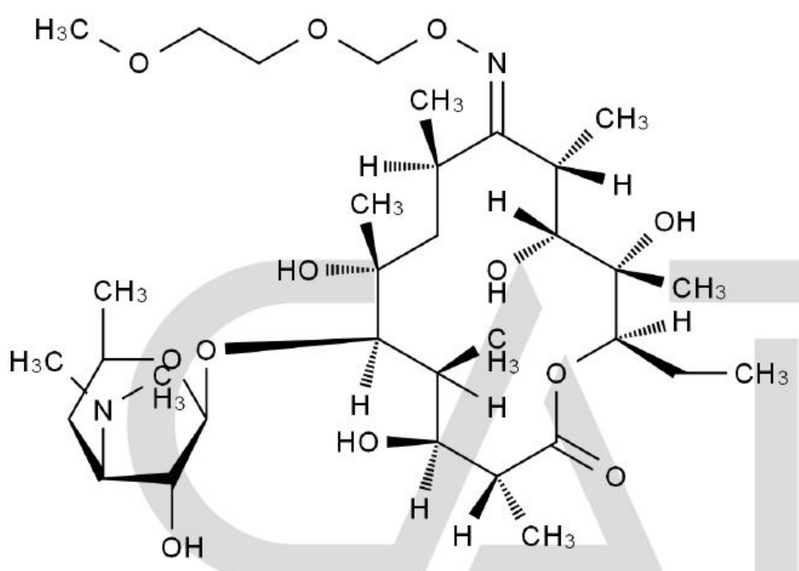
Certificate of Analysis

Reference Material & Standard

Product Name:	Roxithromycin EP Impurity B	**Catalogue Number:**	C4X-13032
Synonyms:	N/A	**Lot Number:**	1023-RH-0041
CAS Number:	214902-82-6	**Expiry Date:**	Oct 15, 2030
Molecular Formula:	$C_{33}H_{62}N_2O_{12}$	**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&UV&HNMR	Confirmed
Purity	HPLC	98.006%
Water Content	Karl Fischer	0.05%
Residual Solvents	NMR	Not detected in NMR
Assay	Mass Balance	98.0%

CATO Research Chemicals Inc.

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: Date: Oct 26, 2026

Reviewed by: Date: Oct 26, 2026

Approved by General Manager: Date: Oct 26, 2026

CATO Research Chemicals Inc.