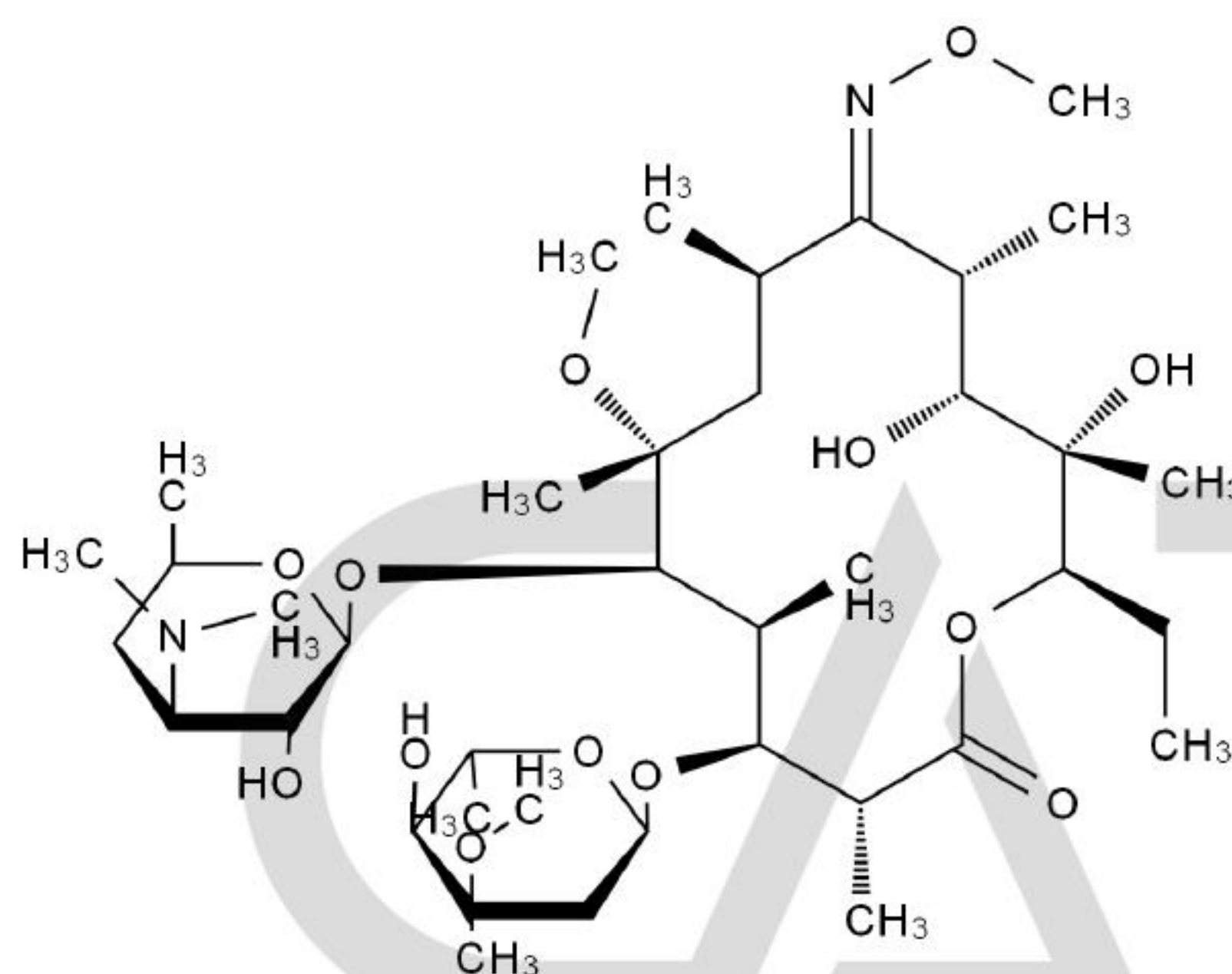


Certificate of Analysis

Reference Material & Standard

Product Name:	Clarithromycin EP Impurity O	Catalogue Number:	C4X-10027
Synonyms:	N/A	Lot Number:	0603-RG-0014
CAS Number:	127252-80-6	Expiry Date:	May 25, 2028
Molecular Formula:	C ₃₉ H ₇₂ N ₂ O ₁₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	776.99	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.375%
Water Content	Karl Fischer	0.59%
Residual Solvents	NMR	0.14% acetonitrile
Assay		98.6%

Comment:

The calculation of the 100% 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: Jun 03, 2025

Date: Jun 03, 2025

Date: Jun 03, 2025

