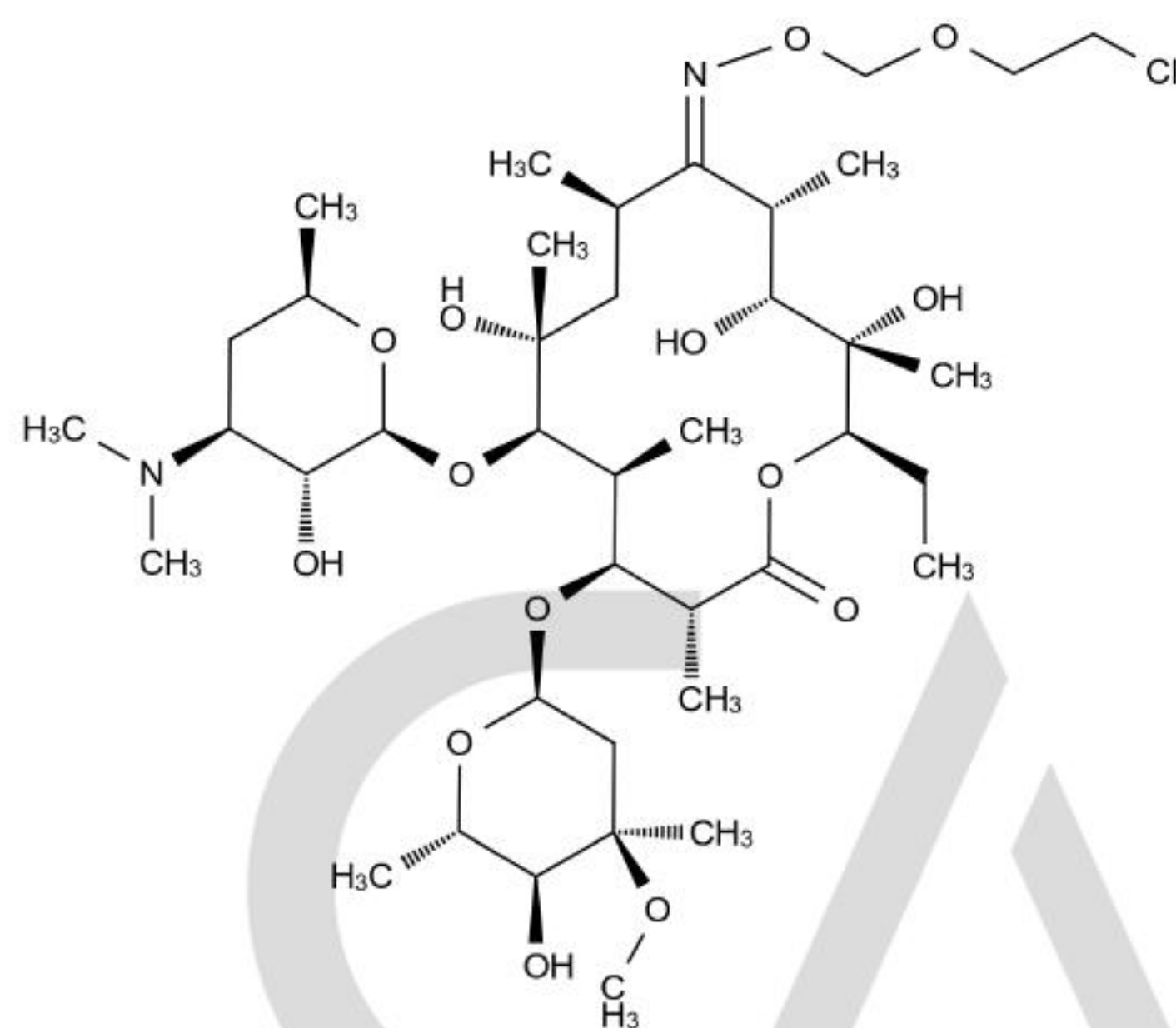


Certificate of Analysis

Reference Material & Standard

Product Name:	Roxithromycin Impurity 24	Catalogue Number:	C4X-130324
Synonyms:	N/A	Lot Number:	0614-RF-0061
CAS Number:	N/A	Expiry Date:	Jun 05, 2027
Molecular Formula:	C ₄₀ H ₇₃ ClN ₂ O ₁₄	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	841.47		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.644%
Water Content	Karl Fischer	0.37%
Residual Solvents	NMR	Not detected in NMR
Assay		98.3%

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 17, 2024

Date: Jun 17, 2024

Date: Jun 17, 2024

