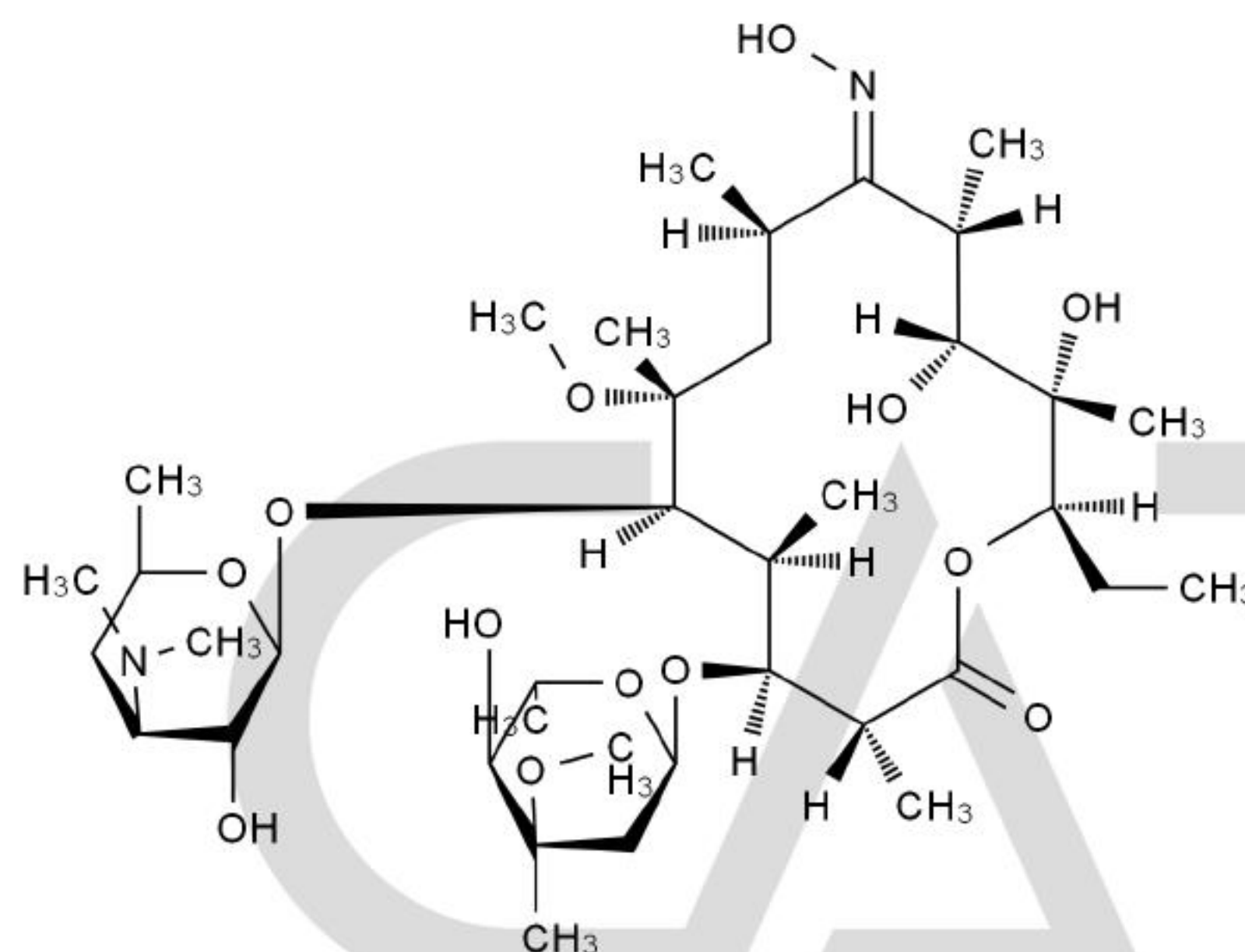


Certificate of Analysis

Reference Material & Standard

Product Name:	Clarithromycin EP Impurity C	Catalogue Number:	C4X-10023
Synonyms:	Clarithromycin impurity C(USP)	Lot Number:	0605-RH-0024
CAS Number:	127253-06-9	Expiry Date:	May 24, 2030
Molecular Formula:	C ₃₈ H ₇₀ N ₂ O ₁₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	762.97	Shipping Condition:	Shipping with Ice Packs

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&UV&CNMR&HNMR	Confirmed
Purity	HPLC	99.678%
Water Content	Karl Fischer	0.51%
Residual Solvents	NMR	0.70% methanol
Assay		98.5%

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:

Reviewed by:

Approved by General Manager:

Date: Jun 11, 2026

Date: Jun 11, 2026

Date: Jun 11, 2026



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