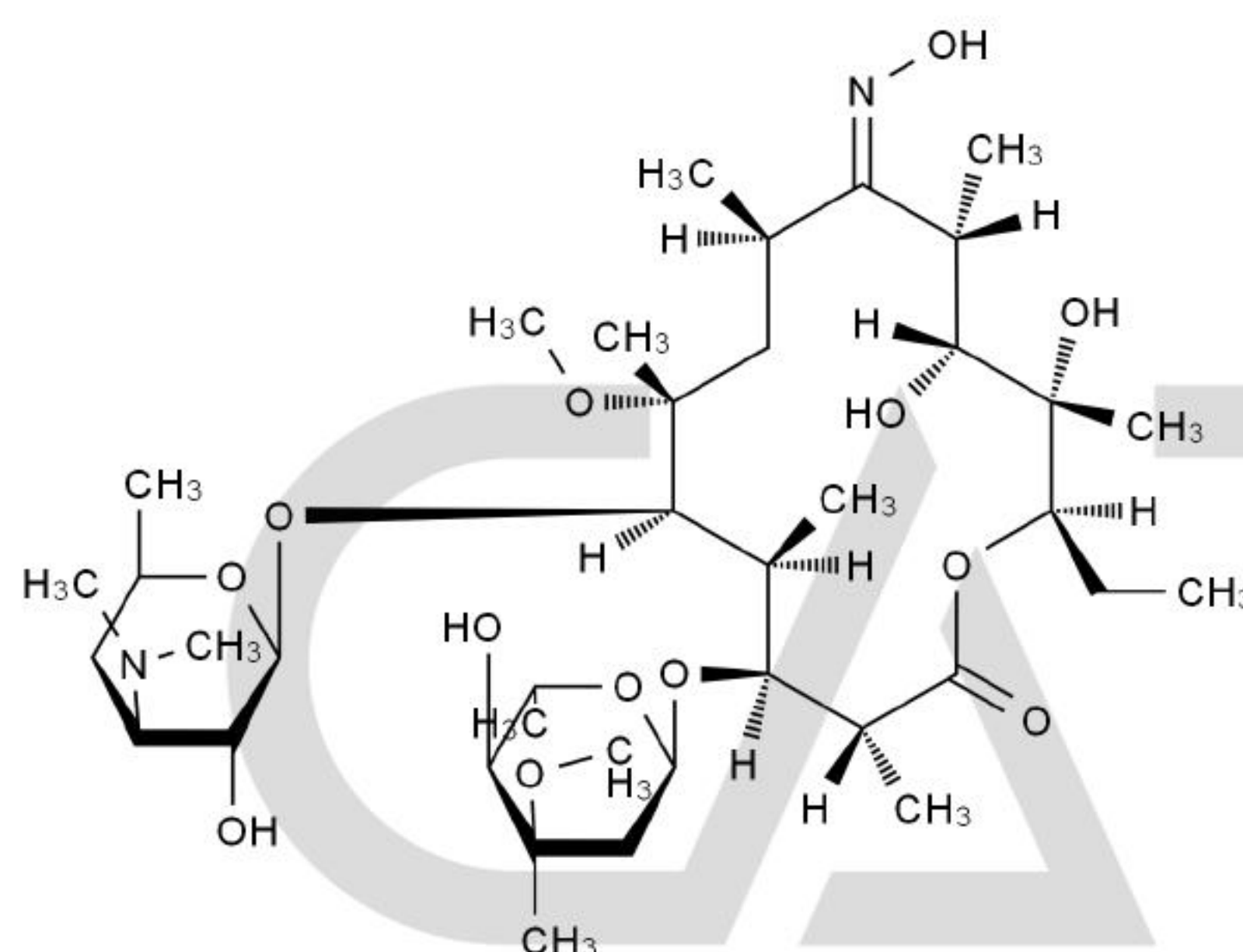


Certificate of Analysis

Reference Material & Standard

Product Name:	Clarithromycin EP Impurity L	Catalogue Number:	C4X-10024
Synonyms:	Clarithromycin Impurity L (USP)/Clarithromycin A (Z)-9-oxime	Lot Number:	0510-RE-0041
CAS Number:	127253-05-8	Expiry Date:	Nov 12, 2029
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&CNMR&HNMR	Confirmed
Purity	HPLC	98.679%
Loss On Drying	TGA	1.7812%
Assay		96.9%

Comment:

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

Assay (%) = (100% - Loss On Drying) * Purity HPLC (%) / 100%

Loss On Drying is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Nice

Reviewed by:

Koi

Approved by General Manager:

David

Date: Dec 01, 2025

Date: Dec 01, 2025

Date: Dec 01, 2025



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