

Certificate of Analysis

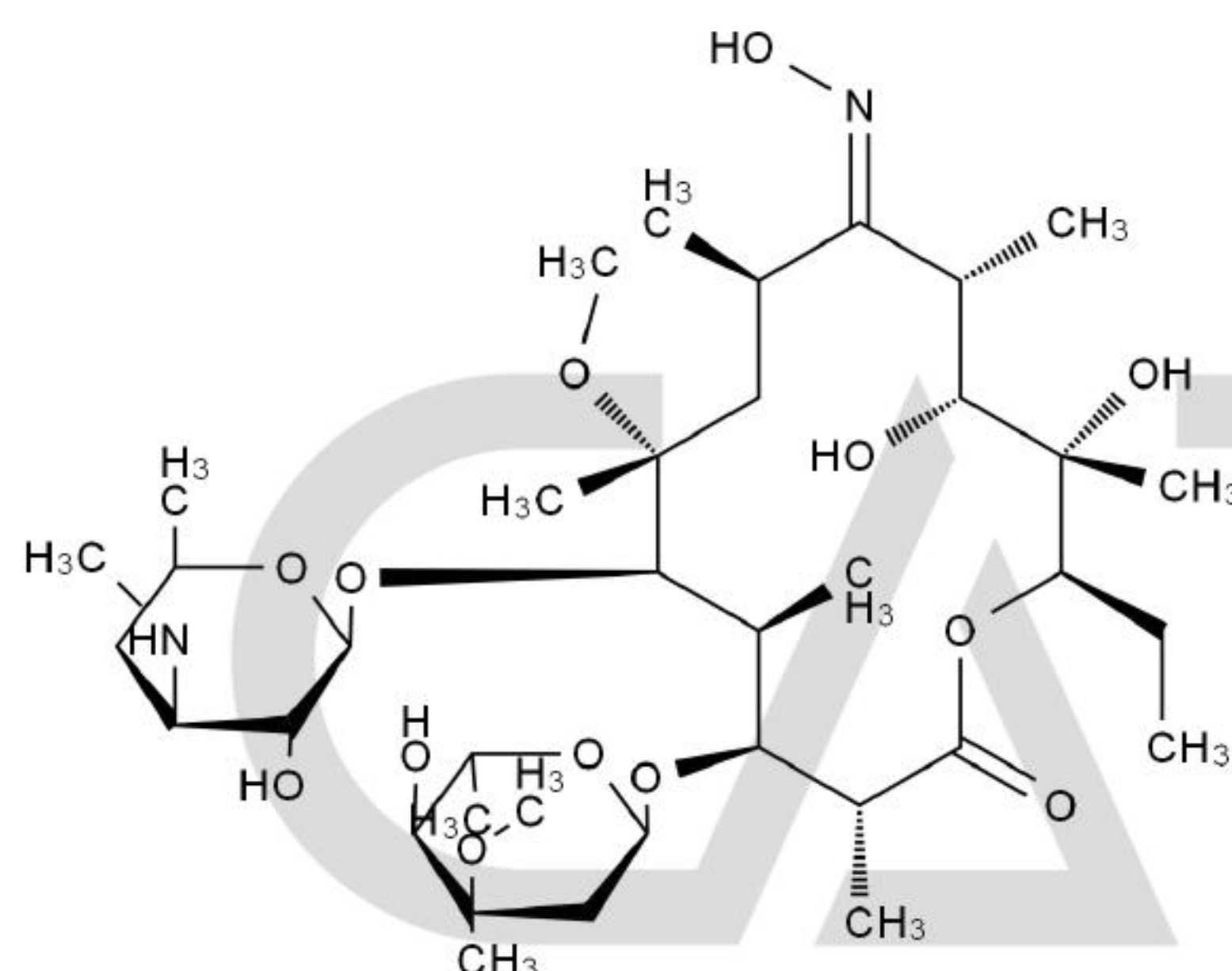
Reference Material & Standard

Product Name:	Clarithromycin EP Impurity M	Catalogue Number:	C4X-10025
Synonyms:	Clarithromycin impurity M(USP)	Lot Number:	0227-RF-0052
CAS Number:	127182-43-8	Expiry Date:	Nov 12, 2029
Molecular Formula:	C ₃₇ H ₆₈ N ₂ O ₁₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	748.94	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	97.900%
Water Content	Karl Fischer	0.78%
Assay		97.1%

Comment:

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

Assay (%) = (100% - Water Content) * Purity HPLC (%) / 100%

Water Content is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Nov 13, 2025

Date: Nov 14, 2025

Date: Nov 14, 2025



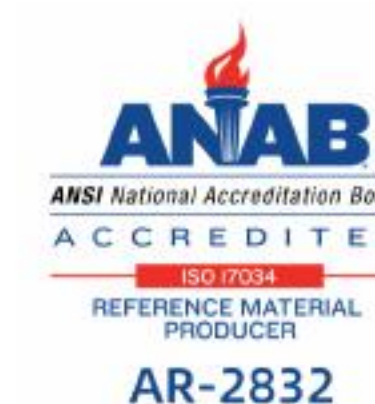
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