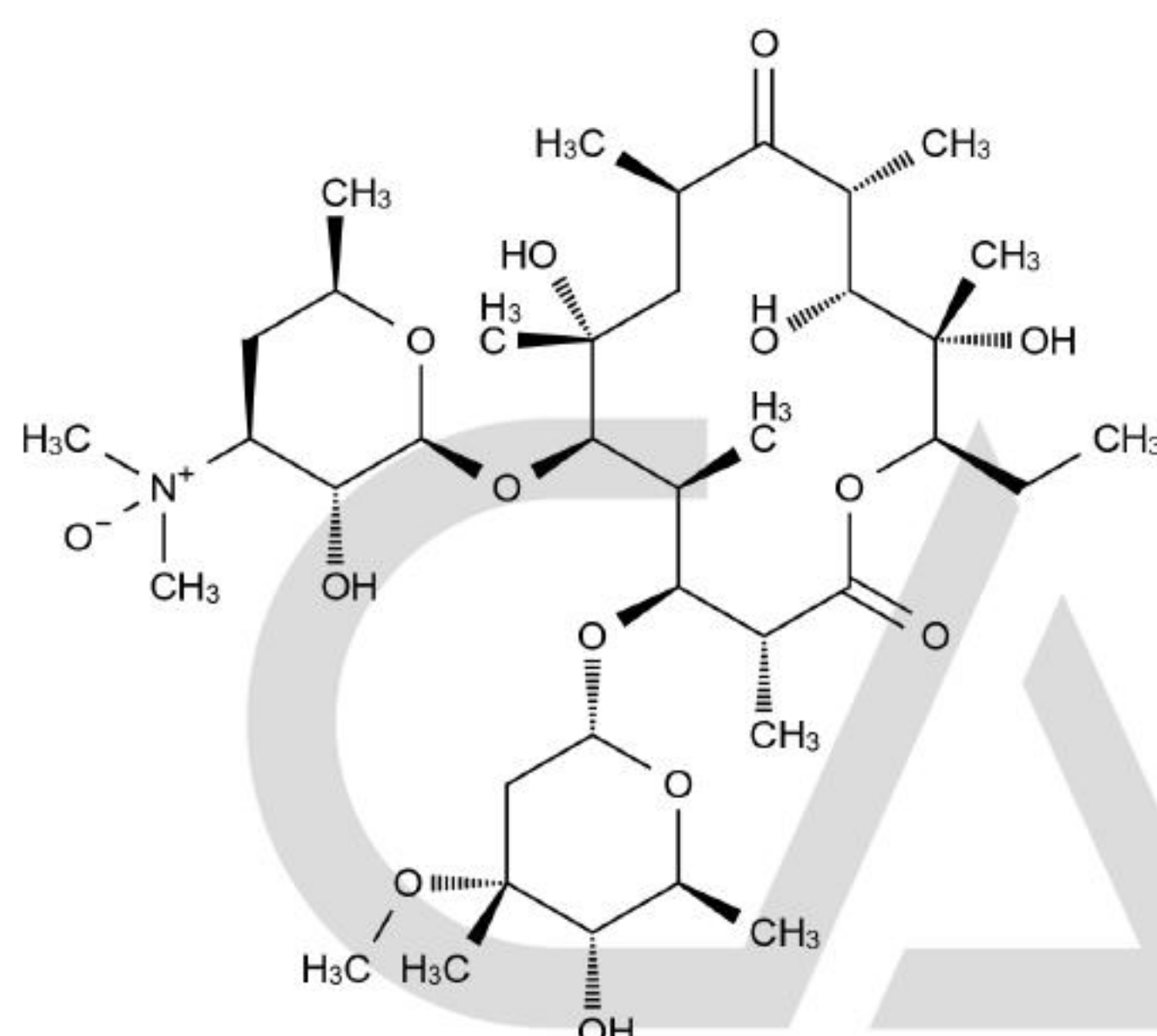


Certificate of Analysis

Reference Material & Standard

Product Name:	Erythromycin EP Impurity H(Erythromycin A N-oxide)	Catalogue Number:	C4X-100115
Synonyms:	Erythromycin A N-oxide	Lot Number:	0909-RG-0120
CAS Number:	992-65-4	Expiry Date:	Aug 21, 2029
Molecular Formula:	C ₃₇ H ₆₇ NO ₁₄	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	749.93		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	95.909%
Water Content	Karl Fischer	1.13%
Residual Solvents	NMR	Not detected in NMR
Assay		94.8%

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:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Sep 10, 2025

Date: Sep 10, 2025

Date: Sep 10, 2025



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