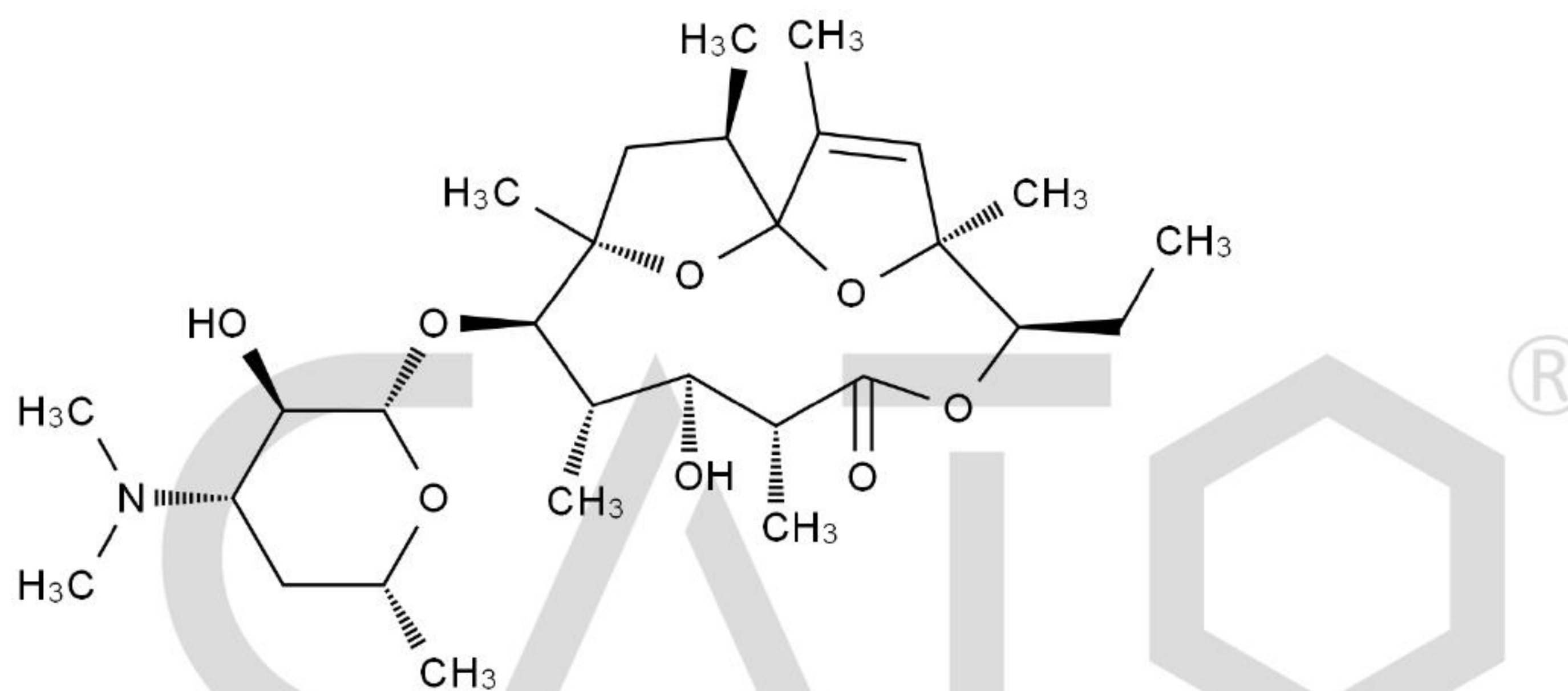


Certificate of Analysis

Reference Material & Standard

Product Name:	Erythromycin EP Impurity I(Erythralosamine)	Catalogue Number:	C4X-100116
Synonyms:	N/A	Lot Number:	0421-RG-0069
CAS Number:	546-57-6	Expiry Date:	Apr 16, 2029
Molecular Formula:	C ₂₉ H ₄₉ NO ₈	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	539.70		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	98.026%
Water Content	Karl Fischer	0.22%
Residual Solvents	NMR	Not detected in NMR
Assay		97.8%

Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$\text{Assay (\%)} = (100\% - \text{Water Content} - \text{Residual Solvents}) * \text{Purity HPLC (\%)} / 100\%$

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 03, 2025

Date: Sep 03, 2025

Date: Sep 03, 2025

