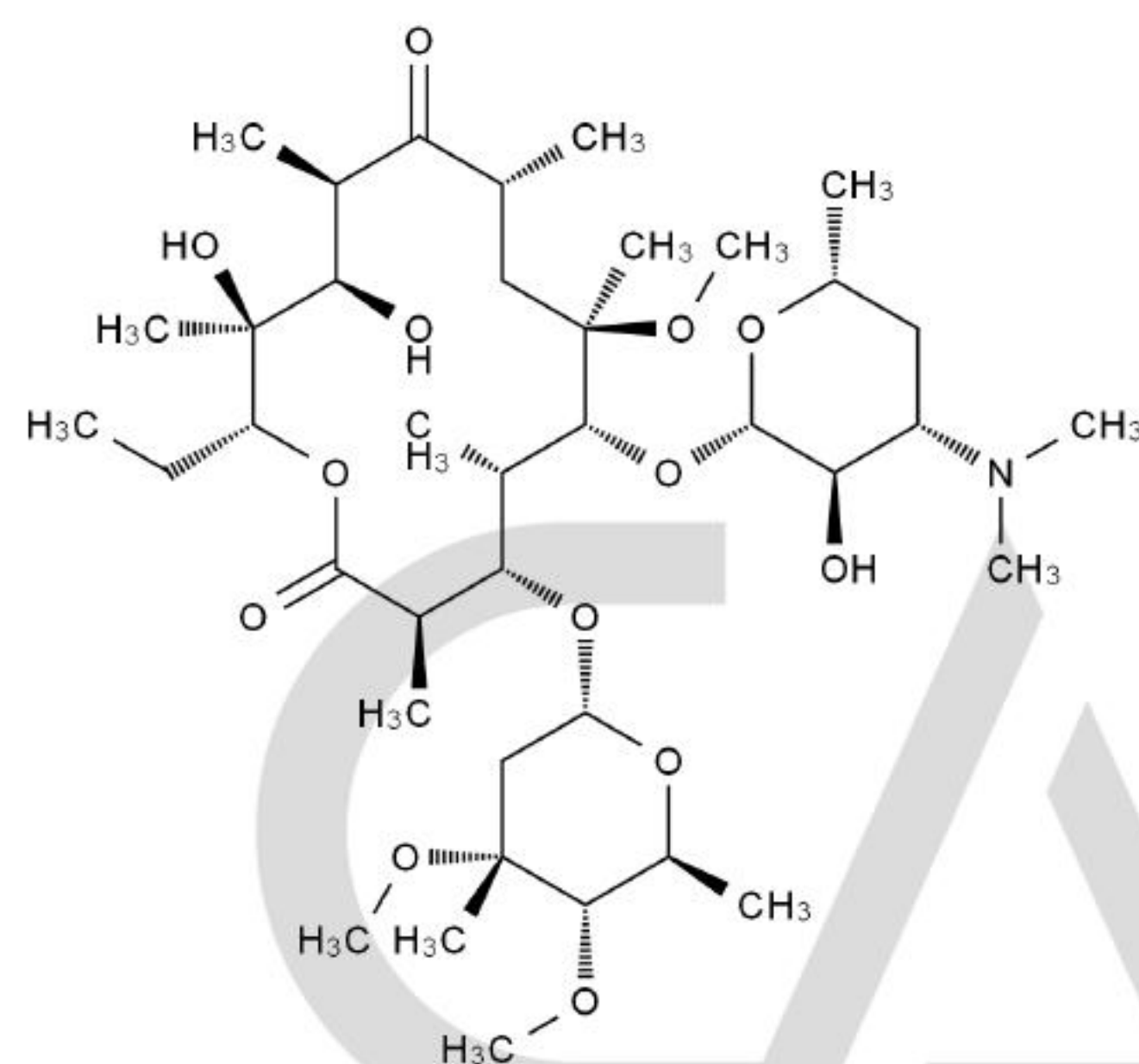


Certificate of Analysis

Reference Material & Standard

Product Name:	Clarithromycin EP Impurity P	Catalogue Number:	C4X-100215
Synonyms:	Clarithromycin impurity P(USP)	Lot Number:	0220-RG-0063
CAS Number:	123967-58-8	Expiry Date:	Jan 15, 2027
Molecular Formula:	C39H71NO13	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	761.98	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&UV&HNMR	Confirmed
Purity	HPLC	95.04%
Residue on Ignition	TGA	0.88%
Loss On Drying	TGA	0.23%
Assay		94.0%

Comment:

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

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

Residue on Ignition and Loss On Drying 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: Feb 24, 2025

Date: Feb 24, 2025

Date: Feb 24, 2025

