

Certificate of Analysis

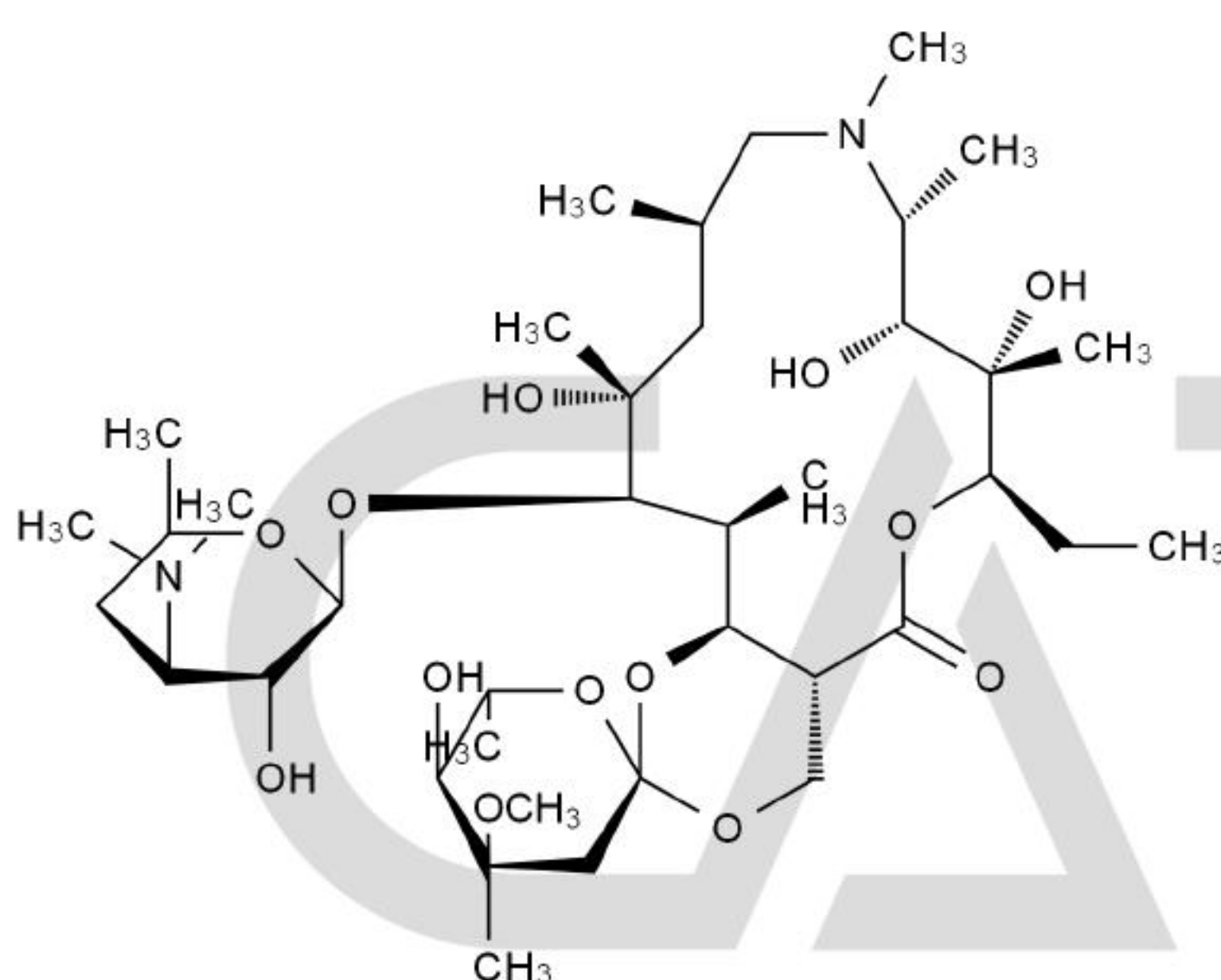
Reference Material & Standard

Product Name:	Azithromycin EP Impurity K	Catalogue Number:	C4X-100311
Synonyms:	N/A	Lot Number:	0306-RH-0080
CAS Number:	N/A	Expiry Date:	Apr 23, 2028
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

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	96.85%
Loss On Drying	TGA	1.134%
Assay		95.8%

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:

Reviewed by:

Approved by General Manager:

Date: Mar 09, 2026

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