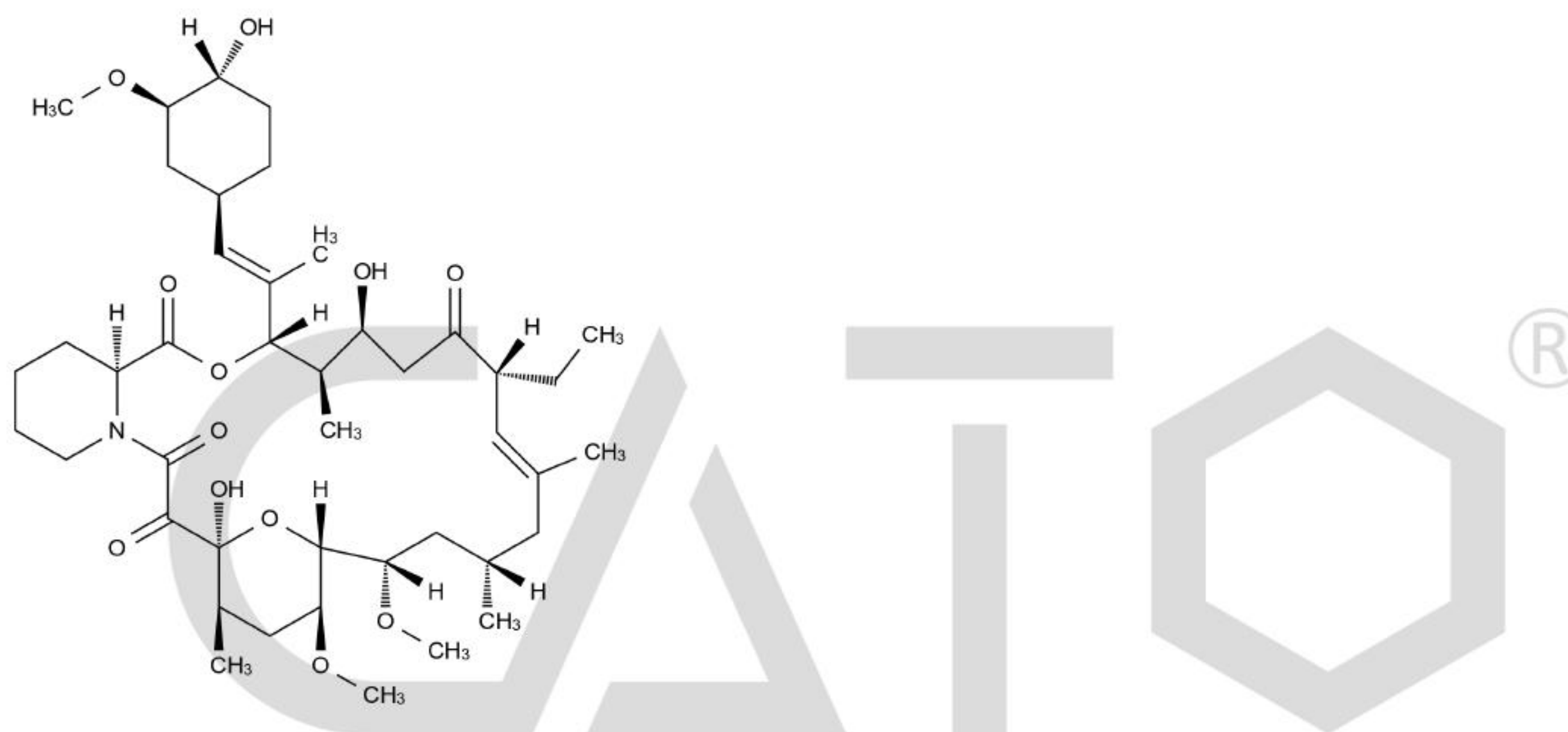


Certificate of Analysis

Reference Material & Standard

Product Name:	Tacrolimus EP Impurity B	Catalogue Number:	C4X-130045
Synonyms:	N/A	Lot Number:	0910-RG-0034
CAS Number:	N/A	Expiry Date:	Sep 06, 2028
Molecular Formula:	C ₄₃ H ₆₉ NO ₁₂	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	792.01		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	96.13%
Loss On Drying	TGA	0.524%
Assay		95.6%

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:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Sep 16, 2025

Date: Sep 16, 2025

Date: Sep 16, 2025



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