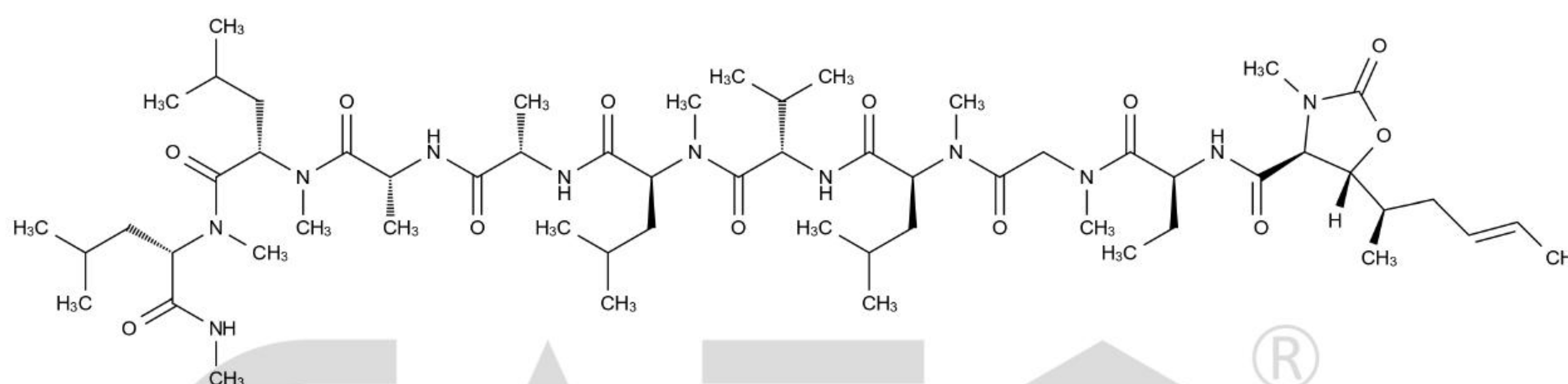


Certificate of Analysis

Reference Material & Standard

Product Name:	Cyclosporin Impurity 15	Catalogue Number:	C4X-131115
Synonyms:	N/A	Lot Number:	0826-RF-0037
CAS Number:	1907654-63-0	Expiry Date:	Sep 20, 2026
Molecular Formula:	C ₅₈ H ₁₀₃ N ₁₁ O ₁₂	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	1146.50		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	94.7151%
Water Content	Karl Fischer	2.70%
Residual Solvents	NMR	Not detected in NMR
Assay		92.2%

Comment:

- The compound contains 4.9% isomeric impurity(RT 20.46)according to its HPLC and LC-MS.
- 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: Aug 29, 2024

Date: Aug 29, 2024

Date: Aug 29, 2024

