

Certificate of Analysis

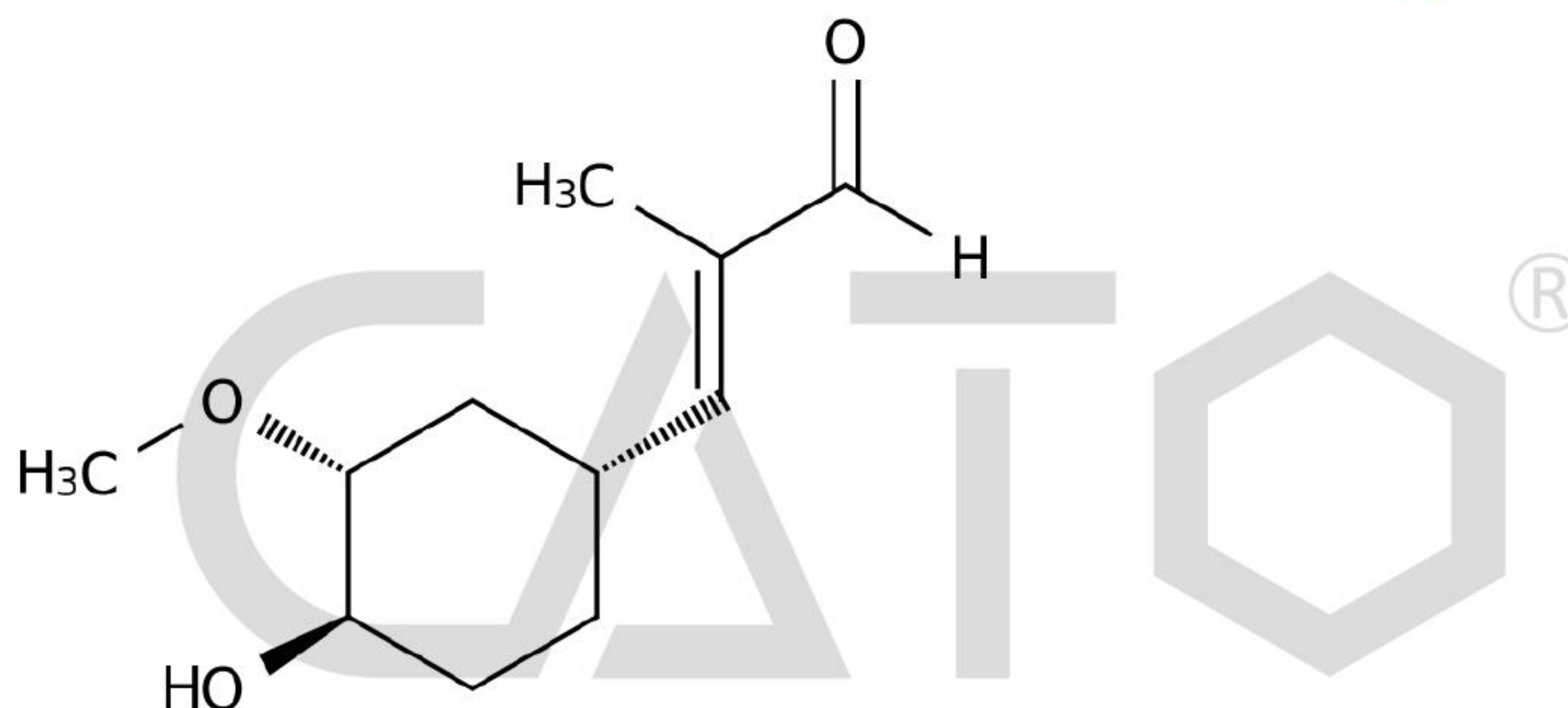
Reference Material & Standard

Product Name:	Tacrolimus Impurity 4	Catalogue Number:	C4X-13004
Synonyms:	N/A	Lot Number:	0508-RC-0034
CAS Number:	109466-74-2	Expiry Date:	Apr 16, 2023
Molecular Formula:	C ₁₁ H ₁₈ O ₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	198.26		

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.0696%
Water Content	Karl Fischer	1.2%
Residual Solvents	NMR	0.3% n-hexane
Specific Rotation		[α] _D ^{25.0} (c=0.49, CHCl ₃) /-34.1°
Assay		97.6%

Comment:

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

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Debia

Reviewed by:

Debia

Approved by General Manager:

David

Date: May 08, 2021

Date: May 10, 2021

Date: May 10, 2021



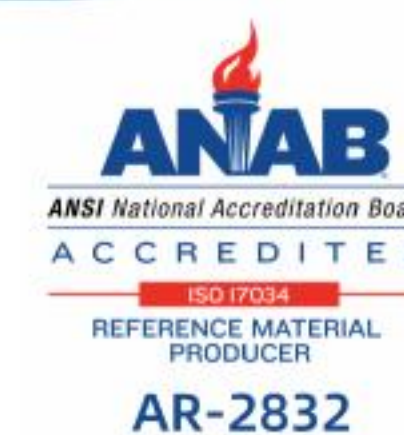
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