

CERTIFICATE OF ANALYSIS

(Certificate No. KME014004-01)

Release Date: 01/08/2025

Re-test Date: 31/07/2028

Everolimus Impurity A

Identification

Chemical Name :

(1R,9S,12S,15R,16E,18R,19R,21R,23S,24E,26E,28E,30S,32S,35R)-1,18-dihydroxy-12-[(2R)-1-[(1S,3R,4R)-4-hydroxy-3-methoxycyclohexyl]propan-2-yl]-19,30-dimethoxy-15,17,21,23,29,35-hexamethyl-11,36-dioxo-4-azatricyclo[30.3.1.04,9]hexatriaconta-16,24,26,28-tetraene-2,3,10,14,20-pentone (as per EP)

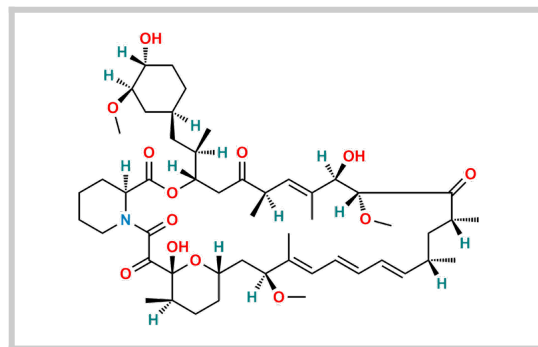
Alt. Name : Sirolimus ; Rapamycin

CAT No. : KME014004

CAS No. : 53123-88-9

Molecular Formula : C₅₁H₇₉NO₁₃

Molecular Weight : 914.2



Analytical Information

Batch No. : EVE-EP-IMP-A-019-336

Description : White Solid

HPLC Purity : 98.52 %

Weight Loss By TGA : 0.33 %

% Potency : 98.19 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

¹³C NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 0.33(Weight Loss By TGA)] x [98.52(HPLC Purity)]/100 = 98.19 %

-Re-tested on 01.08.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		05/08/2025
Reviewed & Approved By	Quality Control	Jatin Patel		05/08/2025

Attachments : COA, HPLC, MASS, ¹HNMR, ¹³CNMR, IR and TGA