

CERTIFICATE OF ANALYSIS

(Certificate No. KME014007-01)

Release Date: 01/08/2025

Re-test Date: 31/07/2028

Everolimus Impurity D

Identification

Chemical Name :

(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)-9,10,12,13,14,21,22,23,24,25,26,27,32,33,34,34a-Hexadecahydro-27-hydroxy-9-(2-hydroxyethoxy)-3-[(1R)-2-[(1S,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylethyl]-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-23,27-epoxy-3H-pyrido[2,1-c][1,4]-oxaazacyclohentriacontine-1,5,11,28,29(4H,6H,31H)-pentone (as per USP)

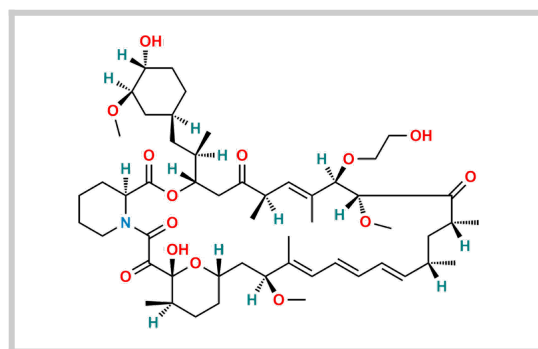
Alt. Name : 9-O-Hydroxyethyl sirolimus (USP) ;
18-O-hydroxyethyl sirolimus

CAT No. : KME014007

CAS No. : 2760174-96-5

Molecular Formula : C53H83NO14

Molecular Weight : 958.2



Analytical Information

Batch No. : EVE-EP-IMP-D-019-338

Description : Off White Solid

HPLC Purity : 97.47 %

Weight Loss By TGA : 0.85 %

% Potency : 96.64 %

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 - 0.85(Weight Loss By TGA)] x [97.47(HPLC Purity)]/100 = 96.64 %
-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