CERTIFICATE OF ANALYSIS

(Certificate No. KME014007-01)

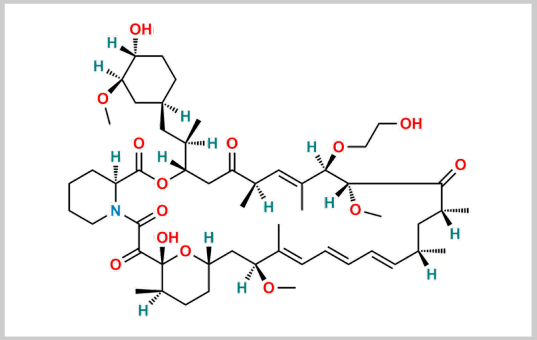
Release Date: 01/08/2025 **Re-test Date:** 31/07/2028

Everolimus EP 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	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 97.47 %	**IR**	: Confirm
Weight Loss By TGA	: 0.85 %	**1H NMR**	: Confirm
% Potency	: 96.64 %	**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