CERTIFICATE OF ANALYSIS

(Certificate No. KME014005-01)

Release Date: 09/01/2025 **Re-test Date:** 08/01/2028

Everolimus Impurity B

Identification

Chemical Name :
(2S)-1-[[(2R,3R,6S)-2-hydroxy-6-[(2S,3E,5E,7E,9S,11R,13R,14R,15E,17R,19E,21R)-14-hydroxy-22-[(1S,3R,4R)-4-(2-hydroxyethoxy)-3-methoxycyclohexyl]-2,13-dimethoxy-3,9,11,15,17,21-hexamethyl-12,18-dioxodocosa-3,5,7,15,19-pentaen-1-yl]-3-methyloxan-2-yl](oxo)acetyl]piperidine-2-carboxylic acid (as per EP)

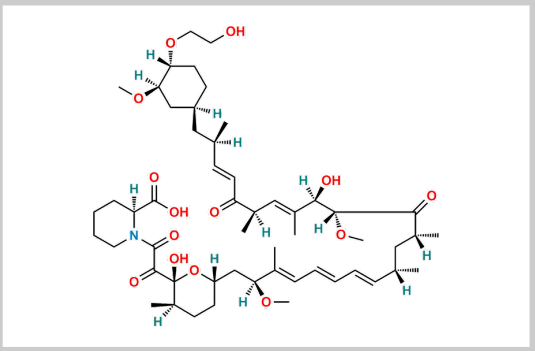
Alt. Name : Everolimus 19-Ene Open-Ring Impurity ; seco Everolimus ; (19E/Z)-seco-[4-O-(2-Hydroxyethyl)] Rapamycin

CAT No. : KME014005

CAS No. : 1062122-63-7

Molecular Formula : C53H83NO14

Molecular Weight : 958.2



Analytical Information

Batch No.	: EVE-EPB-045-053	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 91.99 %	**IR**	: Confirm
Weight Loss By TGA	: 0.88 %	**1H NMR**	: Confirm
% Potency	: 91.18 %	**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 - 0.88(Weight Loss By TGA)] x [91.99(HPLC Purity)]/100 = 91.18 %
-Re-tested on 09.01.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Ravi Sakhiya		16/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		16/01/2025

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