CERTIFICATE OF ANALYSIS

(Certificate No. KME014009-01)

Release Date: 28/07/2025 **Re-test Date:** 27/07/2028

Everolimus Impurity E

Identification

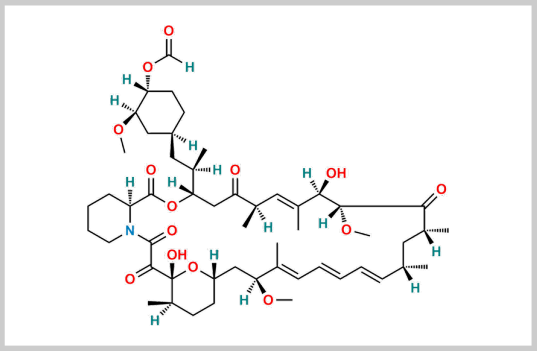
Chemical Name :
(1R,2R,4S)-4-[(2R)-2-[(1R,9S,12S,15R,16E,18R,19R,21R,23S,24E,26E,28E,30S,32S,35R)-1,18-dihydroxy-19,30-dimethoxy-15,17,21,23,29,35-hexamethyl-2,3,10,14,20-pentaoxo-11,36-dioxa-4-azatricyclo[30.3.1.04,9]hexatriaconta-16,24,26,28-tetraen-12-yl]propyl]-2-methoxycyclohexyl formate (as per EP)

CAT No. : KME014009

CAS No. : 1237826-25-3

Molecular Formula : C52H79NO14

Molecular Weight : 942.2



Analytical Information

Batch No.	: EVE-EP-IMP-E-019-339	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 90.96 %	**IR**	: Confirm
Weight Loss By TGA	: 0.96 %	**1H NMR**	: Confirm
% Potency	: 90.09 %	**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 - 0.96(Weight Loss By TGA)] x [90.96(HPLC Purity)]/100 = 90.09 %
-Re-tested on 28.07.2025

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