CERTIFICATE OF ANALYSIS

(Certificate No. KME014004-01)

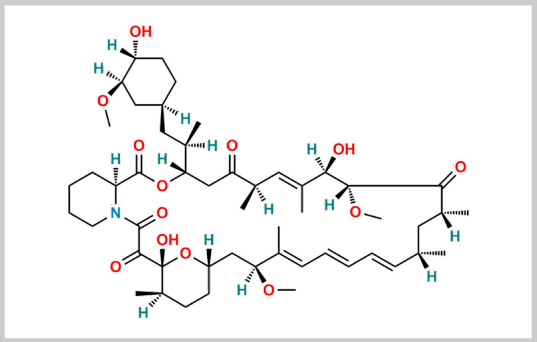
Release Date: 01/08/2025 **Re-test Date:** 31/07/2028

Sirolimus

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-dioxa-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	**Solubility**	: Acetonitrile
Description	: White Solid	**Mass**	: Confirm
HPLC Purity	: 98.52 %	**IR**	: Confirm
Weight Loss By TGA	: 0.33 %	**1H NMR**	: Confirm
% Potency	: 98.19 %		

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		01/08/2025
Reviewed & Approved By	Quality Control	Jatin Patel		01/08/2025

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