CERTIFICATE OF ANALYSIS

(Certificate No. KMR010063-01)

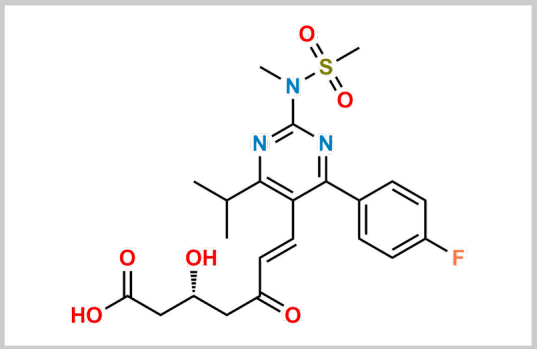
Release Date: 21/02/2025 **Re-test Date:** 20/02/2028

Rosuvastatin EP Impurity C

Identification

Chemical Name :
(3R,6E)-7-[4-(4-fluorophenyl)-2-(N-methylmethanesulfonamido)-6-(propan-2-yl)pyrimidin-5-yl]-3-hydroxy-5-oxohept-6-enoic acid (as per EP);(R,E)-7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)-3-hydroxy-5-oxohept-6-enoic acid (as per USP)

Alt. Name	: Rosuvastatin ketone (USP) ; 5-Oxo Rosuvastatin
CAT No.	: KMR010063
CAS No.	: 1422619-13-3
Molecular Formula	: C22H26FN3O6S
Molecular Weight	: 479.5



Analytical Information

Batch No.	: ROS-EPC-011-016	**Solubility**	: Methanol
Description	: Light Yellow Solid	**Mass**	: Confirm
HPLC Purity	: 99.58 %	**IR**	: Confirm
Weight Loss By TGA	: 0.83 %	**1H NMR**	: Confirm
% Potency	: 98.75 %		

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 - 0.83(Weight Loss By TGA)] x [99.58(HPLC Purity)]/100 = 98.75 %
-Re-tested on 21.02.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/04/2026
Reviewed & Approved By	Quality Control	Jatin Patel		06/04/2026

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