

CERTIFICATE OF ANALYSIS

(Certificate No. KMR010001-01)

Release Date: 25/08/2023

Re-test Date: 24/08/2026

Rosuvastatin Lactone Impurity

Identification

Chemical Name :

N-(4-(4-fluorophenyl)-5-((E)-2-((2S,4R)-4-hydroxy-6-oxotetrahydro-2H-pyran-2-yl)vinyl)-6-isopropylpyrimidin-2-yl)-N-methylmethanesulfonamide

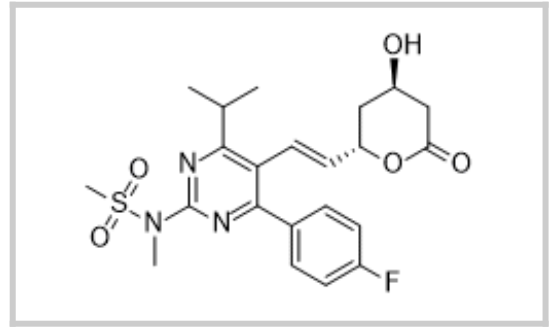
Alt. Name : Rosuvastatin Lactone

CAT No. : KMR010001

CAS No. : 503610-43-3

Molecular Formula : C₂₂H₂₆FN₃O₅S

Molecular Weight : 463.52



Analytical Information

Batch No. : ROS-EPD-011-017

Description : White Solid

HPLC Purity : 96.43 %

Weight Loss By TGA : 0.78 %

% Potency : 95.68 %

Solubility : Methanol

Mass : Confirm

IR : Confirm

¹H 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 - 0.78(Weight Loss By TGA)] x [96.43(HPLC Purity)]/100 = 95.68 %

Remarks : COA Re-generated on 03.07.2024

-Re-tested on 25.08.2023

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		03/07/2024
Reviewed & Approved By	Quality Control	Jatin Patel		03/07/2024

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