

# 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

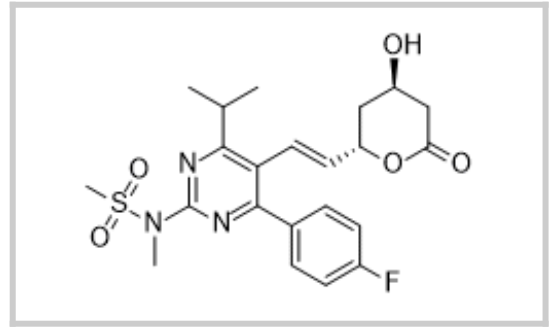
**Alt. Name** : Rosuvastatin Lactone

**CAT No.** : KMR010001

**CAS No.** : 503610-43-3

**Molecular Formula** : C<sub>22</sub>H<sub>26</sub>FN<sub>3</sub>O<sub>5</sub>S

**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

**<sup>1</sup>H 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, <sup>1</sup>HNMR, IR and TGA