

# 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)

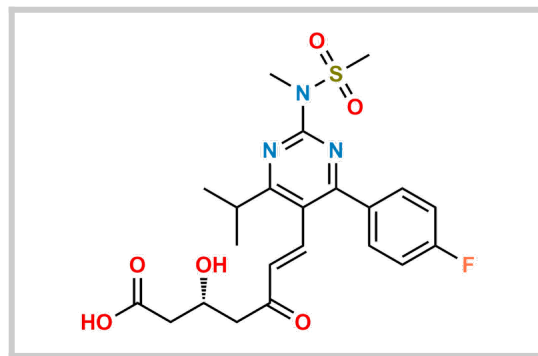
**Alt. Name** : Rosuvastatin ketone (USP) ; 5-Oxo Rosuvastatin

**CAT No.** : KMR010063

**CAS No.** : 1422619-13-3

**Molecular Formula** : C<sub>22</sub>H<sub>26</sub>FN<sub>3</sub>O<sub>6</sub>S

**Molecular Weight** : 479.5



### Analytical Information

**Batch No.** : ROS-EPC-011-016

**Description** : Light Yellow Solid

**HPLC Purity** : 99.58 %

**Weight Loss By TGA** : 0.83 %

**% Potency** : 98.75 %

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

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		06/04/2026
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		06/04/2026

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