

# **CERTIFICATE OF ANALYSIS**

(Certificate No. KMA002010-02)

**Release Date:** 26/05/2025

**Re-test Date:** 25/05/2028

## **Atorvastatin EP Impurity F**

### **Identification**

**Chemical Name :**

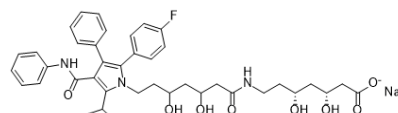
(3R,5R)-7-[[[(3R,5R)-7-[2-(4-Fluorophenyl)-5-(1-methyl ethyl)-3-phenyl- 4-[(phenylamino)carbonyl]-1H-pyrrol-1-yl]- 3,5-dihydroxy-1-oxoheptyl] amino]-3,5-dihydroxy-heptanoic acid sodium salt

**CAT No.** : KMA002010

**CAS No.** : 1371615-56-3

**Molecular Formula** : C<sub>40</sub>H<sub>47</sub>FN<sub>3</sub>O<sub>8</sub> : Na

**Molecular Weight** : 716.82 : 23.0



### **Analytical Information**

**Batch No.** : A002010-102-047

**Description** : Off White Solid

**HPLC Purity** : 95.10 %

**Weight Loss By TGA** : 0.70 %

**% Potency** : 94.43 %

**Solubility** : ACN : Water (1:1)

**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 - 0.70(Weight Loss By TGA)] x [95.10(HPLC Purity)]/100 = 94.43 %

**Recommendation** : Released

|                        | Department      | Name          | Signature | Date       |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By            | Analytical      | Jignesh Patel |           | 17/06/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel   |           | 17/06/2025 |

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, IR and TGA