

# **CERTIFICATE OF ANALYSIS**

(Certificate No. KMA002005-01)

**Release Date:** 13/02/2025

**Re-test Date:** 12/02/2028

## **Atorvastatin Epoxy Pyrrolooxazin 7-Hydroxy Analog**

### **Identification**

**Chemical Name :**

Sodium, (3R)-4-(1b-(4-Fluorophenyl)-7-hydroxy-7-isopropyl-1a-phenyl-7a-(phenylcarbamoyl)hexahydro-1aH-oxireno[2?,3?:3,4]pyrrolo[2,1-b][1,3]oxazin-3-yl)-3-hydroxybutanoate(as per USP)

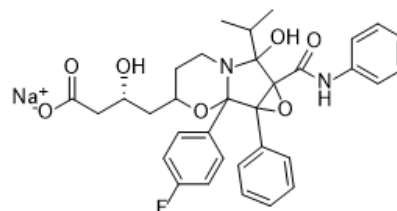
**Alt. Name** : Atorvastatin FX1 Impurity Sodium salt

**CAT No.** : KMA002005

**CAS No.** : 1315629-79-8

**Molecular Formula** : C33H34FN2O7 : Na

**Molecular Weight** : 589.6 : 23.0



### **Analytical Information**

**Batch No.** : ATS-FX1-030-035

**Description** : White Solid

**HPLC Purity** : 99.34 %

**Weight Loss By TGA** : 4.32 %

**% Potency** : 95.05 %

**Solubility** : Acetonitrile

**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 - 4.32(Weight Loss By TGA)] x [99.34(HPLC Purity)]/100 = 95.05 %  
-Re-tested on 13.02.2025.

**Recommendation** : Released

|                        | Department      | Name          | Signature | Date       |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By            | Analytical      | Jignesh Patel |           | 02/05/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel   |           | 02/05/2025 |

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