

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002005-01)

Release Date: 08/04/2023

Re-test Date: 07/04/2026

## Atorvastatin FX1 Impurity

### 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)

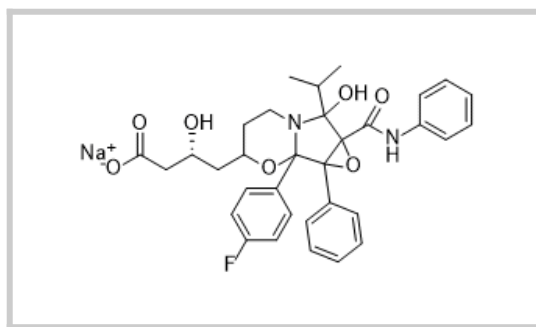
**Alt. Name** : Atorvastatin FX1 Impurity Sodium salt

**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** : 99.35 %

**Weight Loss By TGA** : 3.15 %

**% Potency** : 96.22 %

**Solubility** : ACN

**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** =  $[100 - 3.15(\text{Weight Loss By TGA})] \times [99.35(\text{HPLC Purity})]/100 = 96.22 \%$

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		08/04/2023
Reviewed & Approved By	Quality Control	Jatin Patel		08/04/2023

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