

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002005-01)

Release Date: 13/02/2025

Re-test Date: 12/02/2028

Atorvastatin Epoxy Pyrrolooxazin 7-Hydroxy Analog Sodium salt

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)

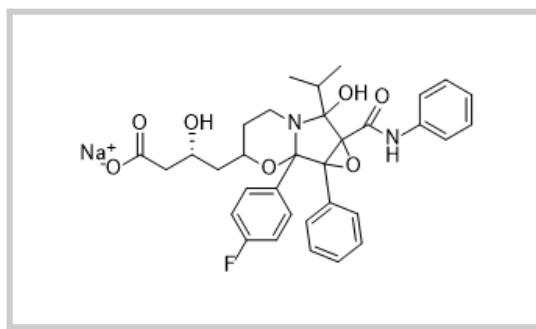
Alt. Name : Atorvastatin FX1 Impurity Sodium salt

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 : 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 = $[100 - 4.32(\text{Weight Loss By TGA})] \times [99.34(\text{HPLC Purity})]/100 = 95.05 \%$
-Re-tested on 13.02.2025.

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 06/03/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 06/03/2025 |

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