

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002066-01)

Release Date: 06/03/2025

Re-test Date: 05/03/2028

Atorvastatin Impurity C

Identification

Chemical Name :

(3R,5R)-7-[2,3-bis(4-fluorophenyl)-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid Sodium salt (as per EP); Sodium (3R,5R)-7-[2,3-Bis(4-fluorophenyl)-5-isopropyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoate (as per USP)

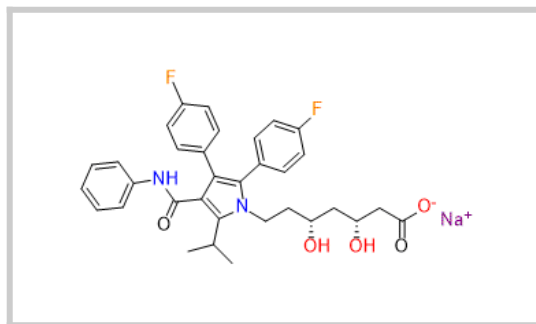
Alt. Name : Atorvastatin USP Related Compound C ; fluoroatorvastatin (EP)

CAT No. : KMA002066

CAS No. : 1807481-00-0

Molecular Formula : C33H34F2N2O5 : Na

Molecular Weight : 576.6 : 23.0



Analytical Information

Batch No. : A002066-091-245

Description : Light Yellow Solid

HPLC Purity : 96.06 %

Weight Loss By TGA : 0.89 %

% Potency : 95.21 %

Solubility : Methanol

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 = $[100 - 0.89(\text{Weight Loss By TGA})] \times [96.06(\text{HPLC Purity})]/100 = 95.21 \%$

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