

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002071-01)

Release Date: 23/06/2025

Re-test Date: 22/06/2028

ATORVASTATIN CA IMPURITY-E - IMP STD

Identification

Chemical Name :

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

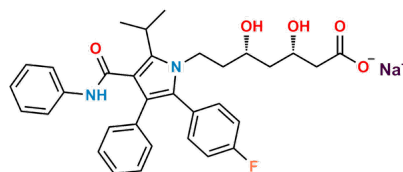
Alt. Name : Ent-Atorvastatin (EP) ; Atorvastatin
USP Related Compound E ;
Atorvastatin (3S,5S)-enantiomer

CAT No. : KMA002071

CAS No. : 1428118-38-0

Molecular Formula : C33H34FN2O5 : Na

Molecular Weight : 557.6 : 23.0



Analytical Information

Batch No. : A002071-102-093

Description : Off White Solid

HPLC Purity : 96.26 %

Weight Loss By TGA : 1.23 %

% Potency : 95.08 %

Solubility : *Refer in
Additional
information

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 - 1.23(Weight Loss By TGA)] x [96.26(HPLC Purity)]/100 = 95.08 %

*Solubility: Insoluble in Water and Freely Soluble in 5mg/1 ml methanol

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 24/06/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 24/06/2025 |

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