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

Alt. Name : Ent-Atorvastatin (EP) ; Atorvastatin

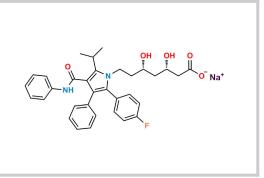
> USP Related Compound E; Atorvastatin (3S,5S)-enantiomer

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 **Solubility** : *Refer in

Additional **Description** : Off White Solid

information

HPLC Purity : 96.26 % **Mass** : Confirm

Weight Loss By TGA : 1.23 % IR : Confirm

% Potency : 95.08 % 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