

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002071-01)

Release Date: 01/06/2025

Re-test Date: 31/05/2028

## Atorvastatin EP Impurity E (Na salt)

### 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)

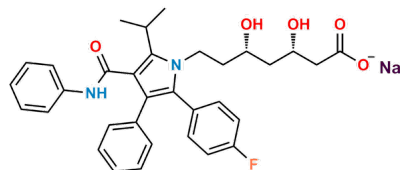
**Alt. Name** : Ent-Atorvastatin (EP) ; Atorvastatin  
USP Related Compound E ;  
Atorvastatin (3S,5S)-enantiomer

**CAT No.** : KMA002071

**CAS No.** : 1428118-38-0

**Molecular Formula** : C33H34FN2O5 : Na

**Molecular Weight** : 557.6 : 23.0



### Analytical Information

**Batch No.** : KMPS/ATS/E/007

**Description** : White crystalline powder

**HPLC Purity** : 98.61 %

**Weight Loss By TGA** : NLT 0.1 %

**% Potency** : 98.51 %

**Solubility** : Acetonitrile :  
Water (1:1)

**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** =  $[100 - 0.1(\text{Weight Loss By TGA})] \times [98.61(\text{HPLC Purity})]/100 = 98.51 \%$

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		01/06/2025
Reviewed & Approved By	Quality Control	Jatin Patel		01/06/2025

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