

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002080-01)

Release Date: 05/05/2025

Re-test Date: 04/05/2028

## Atorvastatin 3-deoxyhept-2- enoic acid Impurity (Impurity J)

### Identification

**Chemical Name :**

(2E,5S)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-5-hydroxyhept-2-enoic acid (as per EP); (S,E)-7-[2-(4-Fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl]-5-hydroxyhept-2-enoic acid (as per USP); Atorvastatin 3-Deoxy-Hept-2-Enoic Acid Na Salt

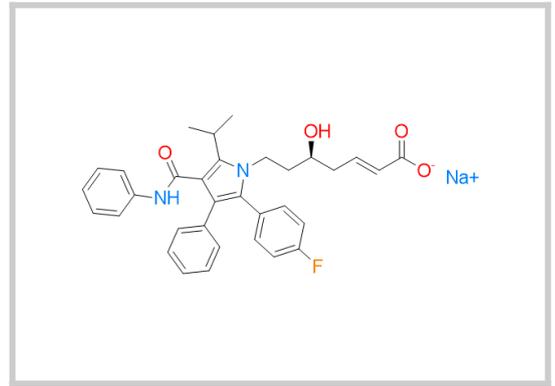
**Alt. Name** : Atorvastatin 3-Deoxy-Hept-2-Enoate (Calcium Salt) (USP) ; 2,3-Anhydro Atorvastatin ; Dehydro Atorvastatin Acid

**CAT No.** : KMA002080

**CAS No.** : 1105067-93-3 (Free Base)

**Molecular Formula** : C33H33FN2O4 : Na

**Molecular Weight** : 540.6 : 23



### Analytical Information

**Batch No.** : A002080-102-008

**Description** : Off White Solid

**HPLC Purity** : 98.47 %

**Weight Loss By TGA** : 1.85 %

**% Potency** : 96.65 %

**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** =  $[100 - 1.85(\text{Weight Loss By TGA})] \times [98.47(\text{HPLC Purity})]/100 = 96.65 \%$

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		05/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		05/05/2025

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