

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

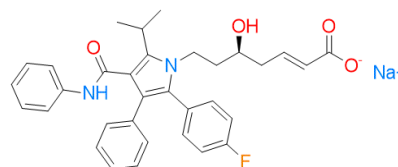
Alt. Name : Atorvastatin 3-Deoxy-Hept-2-Enoate (Calcium Salt) (USP) ; 2,3-Anhydro Atorvastatin ; Dehydro Atorvastatin Acid

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(Weight Loss By TGA)] x [98.47(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