

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002082-01)

Release Date: 26/02/2025

Re-test Date: 25/02/2028

Atorvastatin Diol Methyl Ester Impurity

Identification

Chemical Name :

Methyl (3R,5R)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoate (as per EP); methyl (3R,5R)-7-(2-(4-fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl)-3,5-dihydroxyheptanoate (as per USP)

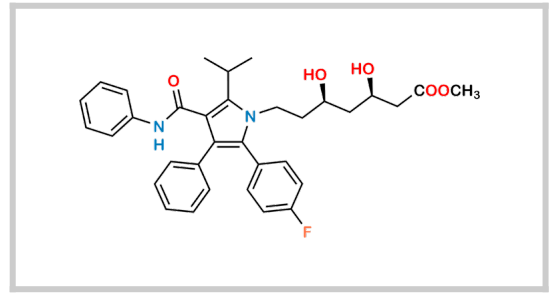
Alt. Name : Atorvastatin Methyl Ester (USP)

CAT No. : KMA002082

CAS No. : 345891-62-5

Molecular Formula : C34H37FN2O5

Molecular Weight : 572.7



Analytical Information

Batch No. : A002082-091-230

Description : Off White Solid

HPLC Purity : 99.70 %

Weight Loss By TGA : 2.05 %

% Potency : 97.66 %

Solubility : Acetonitrile

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 = $[100 - 2.05(\text{Weight Loss By TGA})] \times [99.70(\text{HPLC Purity})]/100 = 97.66 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		01/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		01/03/2025

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