CERTIFICATE OF ANALYSIS

(Certificate No. KMA002083-01)

Release Date: 27/06/2024 **Re-test Date:** 26/06/2027

Atorvastatin EP Impurity M

Identification

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

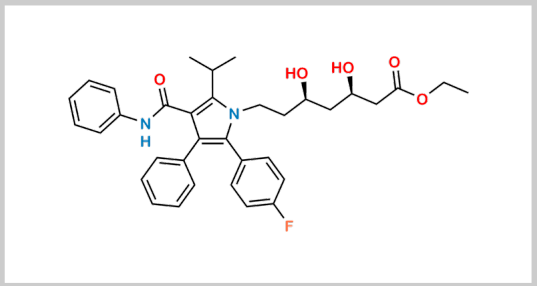
Alt. Name : Atorvastatin Ethyl Ester (USP)

CAT No. : KMA002083

CAS No. : 1146977-93-6

Molecular Formula : C35H39FN2O5

Molecular Weight : 586.7



Analytical Information

Batch No. : ATS-EE-019-028

Description : Off White Solid

HPLC Purity : 98.30 %

Weight Loss By TGA : 0.11 %

% Potency : 98.19 %

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 - 0.11(Weight Loss By TGA)] x [98.30(HPLC Purity)]/100 = 98.19 %
-Re-tested on 27.06.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/06/2024
Reviewed & Approved By	Quality Control	Jatin Patel		27/06/2024

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