

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002083-01)

Release Date: 27/06/2024

Re-test Date: 26/06/2027

## Atorvastatin Ethyl Ester (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)

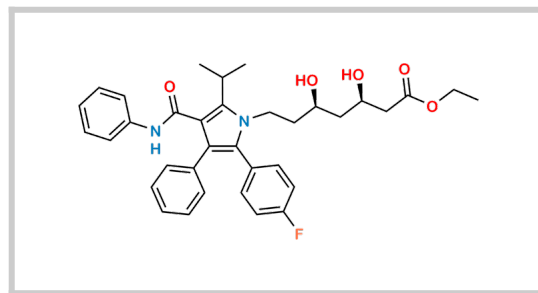
**Alt. Name** : Atorvastatin Ethyl Ester (USP)

**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

**<sup>1</sup>H 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		02/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		02/05/2025

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, IR and TGA