

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002082-01)

Release Date: 26/02/2025

Re-test Date: 25/02/2028

## Atorvastatin Methyl Ester Impurity (Impurity K)

### 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)

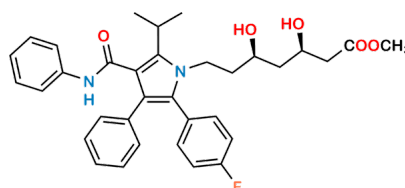
**Alt. Name** : Atorvastatin Methyl Ester (USP)

**CAT No.** : KMA002082

**CAS No.** : 345891-62-5

**Molecular Formula** : C<sub>34</sub>H<sub>37</sub>FN<sub>2</sub>O<sub>5</sub>

**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

**<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 - 2.05(Weight Loss By TGA)] x [99.70(HPLC Purity)]/100 = 97.66 %

**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