

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002085-01)

Release Date: 11/02/2025

Re-test Date: 10/02/2028

## Atorvastatin tert-butyl ester (Impurity N)

### Identification

**Chemical Name :**

Tert-butyl (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)-tert-Butyl 7-(2-(4-fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl)-3,5-dihydroxyheptanoate (as per USP)

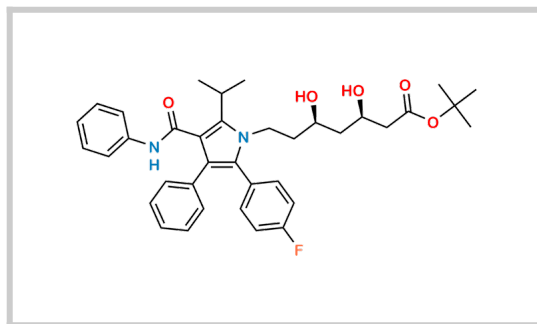
**Alt. Name** : Atorvastatin tert-butyl Ester ;  
Atorvastatin 3-Fluoro t-Butyl Ester

**CAT No.** : KMA002085

**CAS No.** : 134395-00-9

**Molecular Formula** : C<sub>37</sub>H<sub>43</sub>FN<sub>2</sub>O<sub>5</sub>

**Molecular Weight** : 614.9



### Analytical Information

**Batch No.** : KMPS-ATS-TBE-016

**Description** : White solid

**HPLC Purity** : 97.18 %

**Weight Loss By TGA** : 0.30 %

**% Potency** : 96.89 %

**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 - 0.30(Weight Loss By TGA)] x [97.18(HPLC Purity)]/100 = 96.89 %

-Re-tested on 11.02.2025

**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