

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002085-02)

Release Date: 07/03/2026

Re-test Date: 06/03/2029

Atorvastatin tert-Butyl Ester Impurity

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)

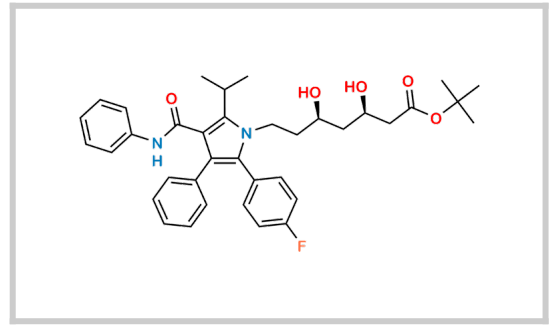
Alt. Name : Atorvastatin tert-butyl Ester ;
Atorvastatin 3-Fluoro t-Butyl Ester

CAT No. : KMA002085

CAS No. : 134395-00-9

Molecular Formula : C37H43FN2O5

Molecular Weight : 614.9



Analytical Information

Batch No. : A002085-114-194

Description : White Solid

HPLC Purity : 99.97 %

Weight Loss By TGA : 0.93 %

% Potency : 99.04 %

Solubility : Methanol

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 = $[100 - 0.93(\text{Weight Loss By TGA})] \times [99.97(\text{HPLC Purity})]/100 = 99.04 \%$

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 10/03/2026 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 10/03/2026 |

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