

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)

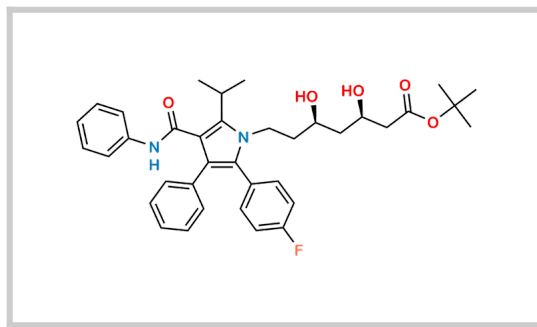
Alt. Name : Atorvastatin tert-butyl Ester ;
Atorvastatin 3-Fluoro t-Butyl Ester

CAT No. : KMA002085

CAS No. : 134395-00-9

Molecular Formula : C37H43FN2O5

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

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 - 0.30(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, ¹HNMR, IR and TGA