CERTIFICATE OF ANALYSIS

(Certificate No. KMA002085-02)

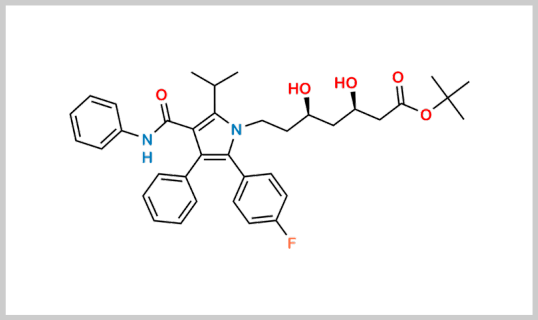
Release Date: 07/03/2026 **Re-test Date:** 06/03/2029

Atorvastatin EP 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.	: A002085-114-194	**Solubility**	: Methanol
Description	: White Soild	**Mass**	: Confirm
HPLC Purity	: 99.97 %	**IR**	: Confirm
Weight Loss By TGA	: 0.93 %	**1H NMR**	: Confirm
% Potency	: 99.04 %		

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(Weight Loss By TGA)] x [99.97(HPLC Purity)]/100 = 99.04 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		07/03/2026
Reviewed & Approved By	Quality Control	Jatin Patel		07/03/2026

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