CERTIFICATE OF ANALYSIS

(Certificate No. KMA002090-01)

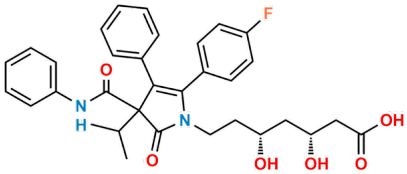
Release Date: 06/03/2025 **Re-test Date:** 05/03/2028

Atorvastatin Pyrrolidone Analog

Identification

Chemical Name :
(3R,5R)-7-[5-(4-fluorophenyl)-2-oxo-4-phenyl-3-(phenylcarbamoyl)-3-(propan-2-yl)-2,3-dihydro-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid (as per EP) ; (3R,5R)-7-[5-(4-Fluorophenyl)-3-isopropyl-2-oxo-4-phenyl-3-(phenylcarbamoyl)-2,3-dihydro-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid (as per USP)

Alt. Name	: Atorvastatin Pyrrolidone Analog (USP) ; Atorvastatin Lactam Impurity ; Atorvastatin Oxo Impurity
CAT No.	: KMA002090
CAS No.	: 906552-18-9
Molecular Formula	: C33H35FN2O6
Molecular Weight	: 574.6



Analytical Information

Batch No.	: ATS-PY-045-068	**Solubility**	: DMF
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 94.49 %	**IR**	: Confirm
Weight Loss By TGA	: 2.91 %	**1H NMR**	: Confirm
% Potency	: 91.74 %		

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 - 2.91(Weight Loss By TGA)] x [94.49(HPLC Purity)]/100 = 91.74 %
-Re-tested on 06.03.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		19/03/2026
Reviewed & Approved By	Quality Control	Jatin Patel		19/03/2026

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