CERTIFICATE OF ANALYSIS

(Certificate No. KMA002090-01)

Release Date: 22/02/2023 **Re-test Date:** 21/02/2026

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

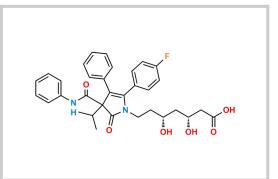
(USP); Atorvastatin Lactam Impurity;

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 : Confirm Mass **HPLC Purity** : 97.58 % IR : Confirm Weight Loss By TGA : 2.90 % 1H NMR : Confirm

% Potency : 94.75 %

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 - 2.90(Weight Loss By TGA)] x [97.58(HPLC Purity)]/100 = 94.75 %

Remarks: COA Re-generated on 11.12.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/03/2025

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