

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)

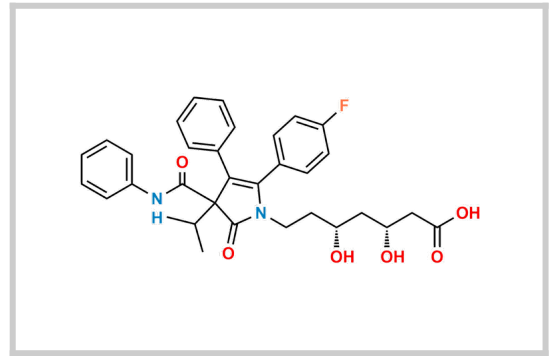
Alt. Name : Atorvastatin Pyrrolidone Analog (USP) ; Atorvastatin Lactam Impurity ; Atorvastatin Oxo Impurity

CAT No. : KMA002090

CAS No. : 906552-18-9

Molecular Formula : C33H35FN2O6

Molecular Weight : 574.6



Analytical Information

Batch No. : ATS-PY-045-068

Description : Off White Solid

HPLC Purity : 97.58 %

Weight Loss By TGA : 2.90 %

% Potency : 94.75 %

Solubility : DMF

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 = $[100 - 2.90(\text{Weight Loss By TGA})] \times [97.58(\text{HPLC Purity})]/100 = 94.75 \%$

Remarks : COA Re-generated on 11.12.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		11/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		11/12/2024

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