

# 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)

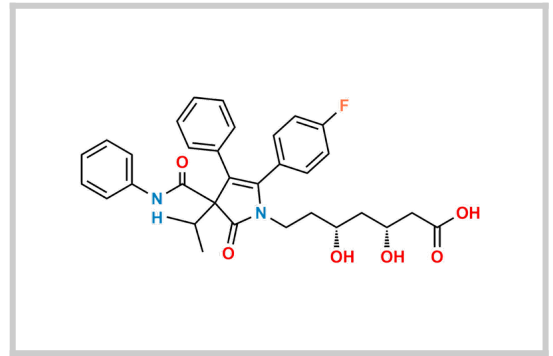
**Alt. Name** : Atorvastatin Pyrrolidone Analog (USP) ; Atorvastatin Lactam Impurity ; Atorvastatin Oxo Impurity

**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