

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002010-01)

Release Date: 20/06/2022

Re-test Date: 19/06/2025

## Atorvastatin Impurity F

### Identification

**Chemical Name :**

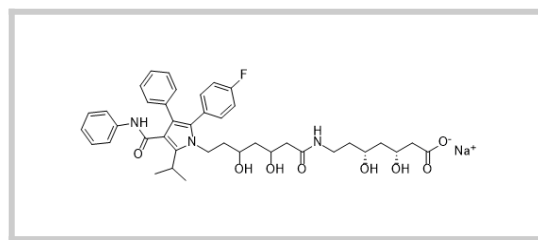
(3R,5R)-7-[[[(3R,5R)-7-[2-(4-Fluorophenyl)-5-(1-methyl ethyl)-3-phenyl- 4-[(phenylamino)carbonyl]-1H-pyrrol-1-yl]- 3,5-dihydroxy-1-oxoheptyl] amino]-3,5-dihydroxy-heptanoic acid sodium salt

CAT No. : KMA002010

CAS No. : 1371615-56-3

Molecular Formula : C<sub>40</sub>H<sub>47</sub>FN<sub>3</sub>O<sub>8</sub> : Na

Molecular Weight : 716.82 : 23.0



### Analytical Information

Batch No. : ATS-IMP-F-030-178

Description : Off White Solid

HPLC Purity : 95.39 %

Weight Loss By TGA : 0.41 %

% Potency : 95 %

Solubility : ACN : Water (1:1)

Mass : Confirm

IR : Confirm

<sup>1</sup>H 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 - 0.41(Weight Loss By TGA)] x [95.39(HPLC Purity)]/100 = 95 %

Remarks : COA Re-generated on 11.06.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		11/06/2024
Reviewed & Approved By	Quality Control	Jatin Patel		11/06/2024

Attachments : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA