

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002010-01)

Release Date: 23/04/2025

Re-test Date: 22/04/2028

Atorvastatin Amide Impurity

Identification

Chemical Name :

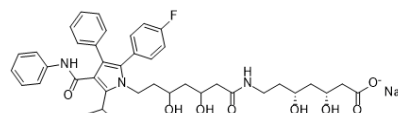
(3R,5R)-7-[[[(3R,5R)-7-[2-(4-Fluorophenyl)-5-(1-methyl ethyl)-3-phenyl- 4-[(phenylamino)carbonyl]-1H-pyrrol-1-yl]- 3,5-dihydroxy-1-oxoheptyl] amino]-3,5-dihydroxy-heptanoic acid sodium salt

CAT No. : KMA002010

CAS No. : 1371615-56-3

Molecular Formula : C₄₀H₄₇FN₃O₈ : Na

Molecular Weight : 716.82 : 23.0



Analytical Information

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

Description : Off White Solid

HPLC Purity : 91.03 %

Weight Loss By TGA : 0.45 %

% Potency : 90.62 %

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 - 0.45(Weight Loss By TGA)] x [91.03(HPLC Purity)]/100 = 90.62 %
-Re-tested on 23.04.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		02/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		02/05/2025

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