

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002011-01)

Release Date: 22/02/2023

Re-test Date: 21/02/2026

rac-3-Oxo atorvastatin Calcium

Identification

Chemical Name :

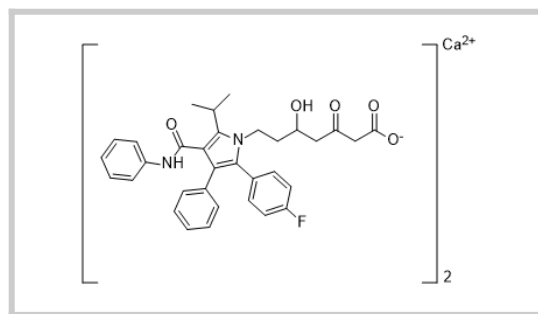
2-(4-Fluorophenyl)-delta-hydroxy-5-(1-methylethyl)-beta-oxo-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic Acid Calcium Salt

CAT No. : KMA002011

CAS No. : 1391052-00-8

Molecular Formula : C₃₃H₃₂FN₂CaO₅

Molecular Weight : 556.62 (M-Ca)



Analytical Information

Batch No. : ATS-PY-045-068

Solubility : DMF

Description : Off white crystalline powder

Mass : Confirm

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 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		14/06/2024
Reviewed & Approved By	Quality Control	Jatin Patel		14/06/2024

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