

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002001-01)

Release Date: 30/11/2023

Re-test Date: 29/11/2026

Atorvastatin Impurity A

Identification

Chemical Name :

(3R,5R)-7-[3-(Phenylcarbamoyl)-5-phenyl-2-isopropyl-4-phenyl-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid calcium

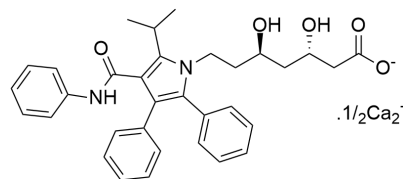
Alt. Name : Desfluoro Atorvastatin Calcium

CAT No. : KMA002001

CAS No. : 433289-83-9

Molecular Formula : C₃₃H₃₅N₂O₅ · 1/2Ca

Molecular Weight : 539.63 : 1/2(40.1)



Analytical Information

Batch No. : ATS-IMP-A-182

Description : Off White Solid

HPLC Purity : 97.02 %

Weight Loss By TGA : 2.21 %

% Potency : 94.88 %

Solubility : Methanol

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 - 2.21(Weight Loss By TGA)] x [97.02(HPLC Purity)]/100 = 94.88 %

Remarks : COA regenerated on 12.09.2024

-Re-tested on 30.11.2023

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		01/12/2025
Reviewed & Approved By	Quality Control	Jatin Patel		01/12/2025

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