

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002088-01)

Release Date: 10/02/2025

Re-test Date: 09/02/2028

Atorvastatin AVE Ketal Impurity

Identification

Chemical Name :

[(4R,6R)-6-[2-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]ethyl]-2,2-dimethyl-1,3-dioxan-4-yl]acetic acid (as per EP)

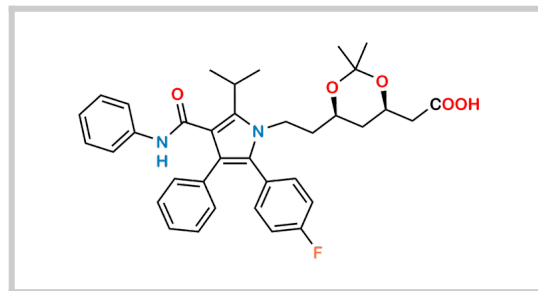
Alt. Name : Atorvastatin Acetonide

CAT No. : KMA002088

CAS No. : 581772-29-4

Molecular Formula : C₃₆H₃₉FN₂O₅

Molecular Weight : 598.7



Analytical Information

Batch No. : ATS-APDACID-019-058

Description : Off White Solid

HPLC Purity : 95.51 %

Weight Loss By TGA : 2.58 %

% Potency : 93.05 %

Solubility : Acetonitrile

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 - 2.58(Weight Loss By TGA)] x [95.51(HPLC Purity)]/100 = 93.05 %
-Re-tested on 10.02.2025.

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		17/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		17/03/2025

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