

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002079-01)

Release Date: 02/05/2025

Re-test Date: 01/05/2028

ATORVASTATIN RELATED COMPOUND I

Identification

Chemical Name :

tert-butyl [(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]acetate (as per EP); tert-Butyl 2-((4R,6R)-6-{2-[2-(4-fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl]ethyl}-2,2-dimethyl-1,3-dioxan-4-yl)acetate (as per USP)

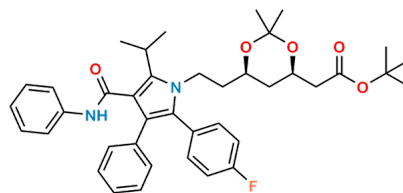
Alt. Name : Atorvastatin USP Related Compound I ; Acetonide Atorvastatin (USP) ; Atorvastatin Acetonide t-Butyl Ester

CAT No. : KMA002079

CAS No. : 125971-95-1

Molecular Formula : C₄₀H₄₇FN₂O₅

Molecular Weight : 654.8



Analytical Information

Batch No. : A002079-102-002

Description : Off White solid

HPLC Purity : 99.74 %

Weight Loss By TGA : 0.59 %

% Potency : 99.15 %

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 - 0.59(Weight Loss By TGA)] x [99.74(HPLC Purity)]/100 = 99.15 %

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