CERTIFICATE OF ANALYSIS

(Certificate No. KMA002079-01)

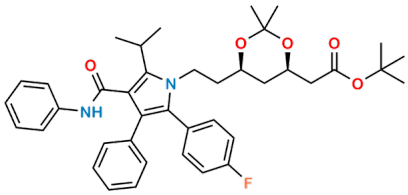
Release Date: 02/05/2025 **Re-test Date:** 01/05/2028

Atorvastatin EP Impurity 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	**Solubility**	: Methanol
Description	: Off White solid	**Mass**	: Confirm
HPLC Purity	: 99.74 %	**IR**	: Confirm
Weight Loss By TGA	: 0.59 %	**1H NMR**	: Confirm
% Potency	: 99.15 %		

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