CERTIFICATE OF ANALYSIS

(Certificate No. KMA002071-01)

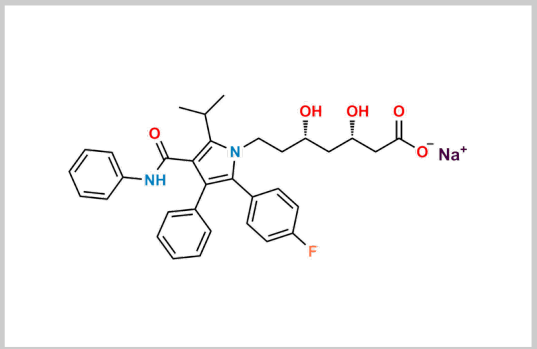
Release Date: 23/06/2025 **Re-test Date:** 22/06/2028

ATORVASTATIN CA IMPURITY-E - IMP STD

Identification

Chemical Name :
(3S,5S)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid Sodium salt (as per EP); Sodium (3S,5S)-7-[2-(4-fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoate (as per USP)

Alt. Name	: Ent-Atorvastatin (EP) ; Atorvastatin USP Related Compound E ; Atorvastatin (3S,5S)-enantiomer
CAT No.	: KMA002071
CAS No.	: 1428118-38-0
Molecular Formula	: C33H34FN2O5 : Na
Molecular Weight	: 557.6 : 23.0



Analytical Information

Batch No.	: A002071-102-093
Description	: Off White Solid
HPLC Purity	: 96.26 %
Weight Loss By TGA	: 1.23 %
% Potency	: 95.08 %
Solubility	: *Refer in Additional information
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 - 1.23(Weight Loss By TGA)] x [96.26(HPLC Purity)]/100 = 95.08 %
*Solubility: Insoluble in Water and Freely Soluble in 5mg/1 ml methanol

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		24/06/2025
Reviewed & Approved By	Quality Control	Jatin Patel		24/06/2025

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