CERTIFICATE OF ANALYSIS

(Certificate No. KMA002063-01)

Release Date: 15/10/2026 **Re-test Date:** 14/10/2029

Atorvastatin EP Impurity B

Identification

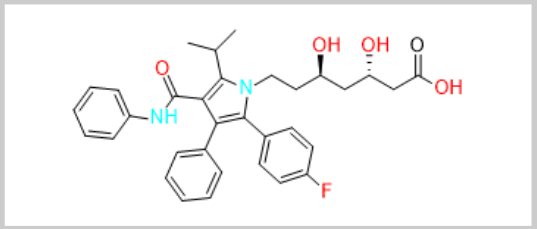
Chemical Name :
(3RS,5SR)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid (as per EP)

CAT No. : KMA002063

CAS No. : 842103-12-2

Molecular Formula : C33H35FN2O5

Molecular Weight : 558.7



Analytical Information

Batch No.	: A002063-136-291	**Solubility**	: ACN : Water (1:1)
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 95.88 %	**IR**	: Confirm
Weight Loss By TGA	: 4.40 %	**1H NMR**	: Confirm
% Potency	: 91.66 %		

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 - 4.40(Weight Loss By TGA)] x [95.88(HPLC Purity)]/100 = 91.66 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		15/10/2026
Reviewed & Approved By	Quality Control	Jatin Patel		15/10/2026

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