

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002137-03)

Release Date: 19/03/2026

Re-test Date: 18/03/2029

Atorvastatin Pyrrolidone Analog Sodium salt (USP)

Identification

Chemical Name :

(3R,5R)-7-[5-(4-Fluorophenyl)-3-isopropyl-2-oxo-4-phenyl-3-(phenylcarbamoyl)-2,3-dihydro-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid Sodium salt (as per USP)

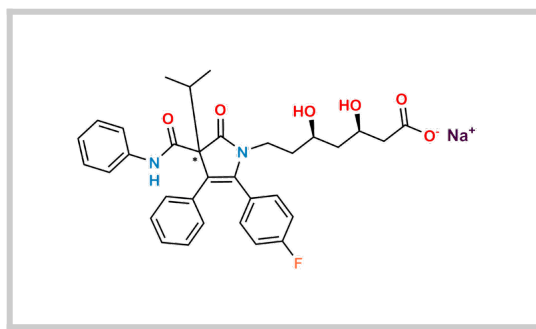
Alt. Name : Atorvastatin Lactam Impurity ;
Atorvastatin Oxo Impurity

CAT No. : KMA002137

CAS No. : 148217-40-7

Molecular Formula : C₃₃H₃₄FN₂O₆ : Na

Molecular Weight : 573.6 : 23.0



Analytical Information

Batch No. : A002137-114-202

Description : Off White Solid

HPLC Purity : 95.50 %

Weight Loss By TGA : 1.11 %

% Potency : 94.44 %

Solubility : Methanol

Mass : Confirm as Na Adduct

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 - 1.11(Weight Loss By TGA)] x [95.50(HPLC Purity)]/100 = 94.44 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		19/03/2026
Reviewed & Approved By	Quality Control	Jatin Patel		19/03/2026

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA