

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002006-01)

Release Date: 20/02/2025

Re-test Date: 19/02/2028

Atorvastatin Impurity-2

Identification

Chemical Name :

Sodium, 4-{6-(4-Fluorophenyl)-7,8-epoxy-6-hydroxy-8a-isopropyl-7-phenyl-8-(phenylcarbamoyl)hexahydro-2H-pyrrolo[2,1-b][1,3]oxazin-2-yl}-3-hydroxybutanoate(as per USP)

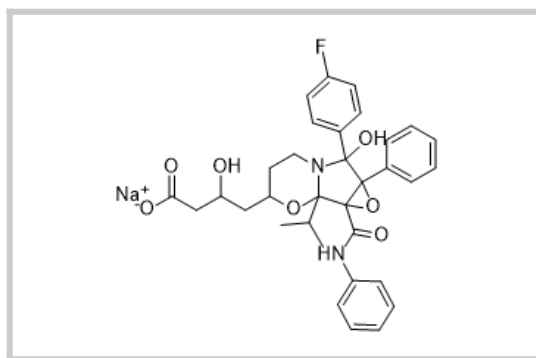
Alt. Name : Atorvastatin Cyclic Isopropyl Impurity ; Atorvastatin FXA Impurity

CAT No. : KMA002006

CAS No. : 1316291-19-6 ; 873950-17-5 (free base)

Molecular Formula : C33H34FN2O7 : Na

Molecular Weight : 589.6 : 23.0



Analytical Information

Batch No. : ATS-FXA-045-147

Description : White solid

HPLC Purity : 98.17 %

Weight Loss By TGA : 3.16 %

% Potency : 95.07 %

Solubility : DMF

Mass : Confirm

IR : Confirm

1H NMR : Confirm

Additional Information

Long Term Storage : Store at -20 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = $[100 - 3.16(\text{Weight Loss By TGA})] \times [98.17(\text{HPLC Purity})]/100 = 95.07 \%$

-Re-tested on 20.02.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		02/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		02/04/2025

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