

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002005-01)

Release Date: 08/04/2023

Re-test Date: 07/04/2026

Atorvastatin FX1 Impurity

Identification

Chemical Name :

Sodium, (3R)-4-(1b-(4-Fluorophenyl)-7-hydroxy-7-isopropyl-1a-phenyl-7a-(phenylcarbamoyl)hexahydro-1aH-oxireno[2?,3?:3,4]pyrrolo[2,1-b][1,3]oxazin-3-yl)-3-hydroxybutanoate(as per USP)

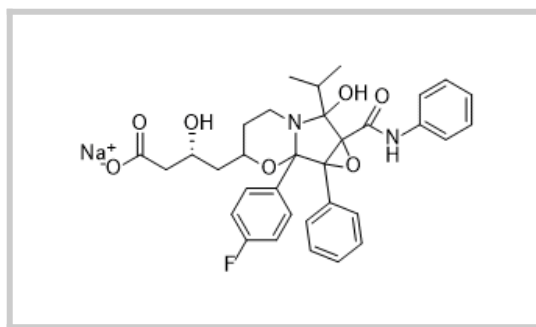
Alt. Name : Atorvastatin FX1 Impurity Sodium salt

CAT No. : KMA002005

CAS No. : 1315629-79-8

Molecular Formula : C33H34FN2O7 : Na

Molecular Weight : 589.6 : 23.0



Analytical Information

Batch No. : ATS-FX1-030-035

Description : White Solid

HPLC Purity : 99.35 %

Weight Loss By TGA : 3.15 %

% Potency : 96.22 %

Solubility : ACN

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 = $[100 - 3.15(\text{Weight Loss By TGA})] \times [99.35(\text{HPLC Purity})]/100 = 96.22 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		08/04/2023
Reviewed & Approved By	Quality Control	Jatin Patel		08/04/2023

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