

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002065-01)

Release Date: 28/11/2023

Re-test Date: 27/11/2026

Atorvastatin Impurity C

Identification

Chemical Name :

(3R,5R)-7-[2,3-bis(4-fluorophenyl)-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid calcium salt (as per EP)(3R,5R)-7-[2,3-Bis(4-fluorophenyl)-5-isopropyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid calcium salt (as per USP)

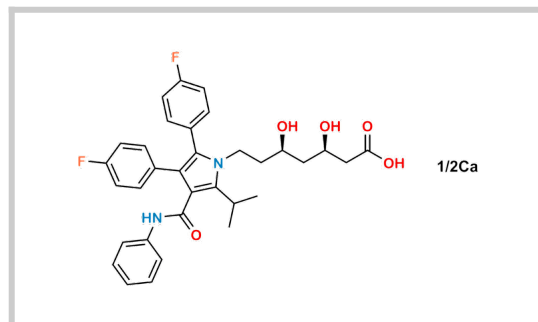
Alt. Name : Atorvastatin USP Related Compound C ; fluoroatorvastatin (EP)

CAT No. : KMA002065

CAS No. : 693793-53-2

Molecular Formula : C33H34F2N2O5 : 1/2(Ca)

Molecular Weight : 576.6 : 1/2(40.1)



Analytical Information

Batch No. : ATS-RC-C-019-059

Description : White Solid

HPLC Purity : 98.69 %

Weight Loss By TGA : 3.49 %

% Potency : 95.25 %

Solubility : THF : Buffer Sol. :
ACN 5:35:60
(V/V/V)***

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 - 3.49(Weight Loss By TGA)] x [98.69(HPLC Purity)]/100 = 95.25 %

-Re-tested on 28.11.2023

***Solubility as per EP

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		03/03/2025
Reviewed & Approved By	Quality Control	Parag Patel		03/03/2025

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