

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002004-01)

Release Date: 12/06/2024

Re-test Date: 11/06/2027

Atorvastatin EP Impurity D

Identification

Chemical Name :

3-(4-Fluorobenzoyl)-2-isobutyryl-3-phenyloxirane-2-carboxylic acid phenylamide

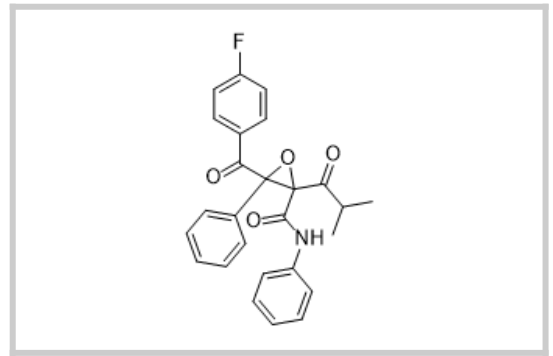
Alt. Name : Atorvastatin USP Related Compound D

CAT No. : KMA002004

CAS No. : 148146-51-4

Molecular Formula : C₂₆H₂₂FNO₄

Molecular Weight : 431.46



Analytical Information

Batch No. : KMPS/ATS/D/006

Description : Off White Solid

HPLC Purity : 95.01 %

Weight Loss By TGA : 0.40 %

% Potency : 94.63 %

Solubility : DMF

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 - 0.40(Weight Loss By TGA)] x [95.01(HPLC Purity)]/100 = 94.63 %

Remarks : Re-tested and Re-generated on 13.06.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		04/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		04/03/2025

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