

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002004-02)

Release Date: 01/12/2025

Re-test Date: 30/11/2028

Atorvastatin Impurity D

Identification

Chemical Name :

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

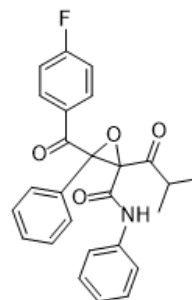
Alt. Name : Atorvastatin USP Related Compound D

CAT No. : KMA002004

CAS No. : 148146-51-4

Molecular Formula : C₂₆H₂₂FNO₄

Molecular Weight : 431.46



Analytical Information

Batch No. : A002004-114-035

Solubility : DMF

Description : White solid

Mass : Confirm

HPLC Purity : 98.65 %

IR : Confirm

Weight Loss By TGA : 0.63 %

¹H NMR : Confirm

% Potency : 98.03 %

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 - 0.63(Weight Loss By TGA)] x [98.65(HPLC Purity)]/100 = 98.03 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		01/12/2025
Reviewed & Approved By	Quality Control	Jatin Patel		01/12/2025

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