CERTIFICATE OF ANALYSIS

(Certificate No. KMA002067-01)

Release Date: 29/11/2023 **Re-test Date:** 28/11/2026

Atorvastatin EP Impurity D

Identification

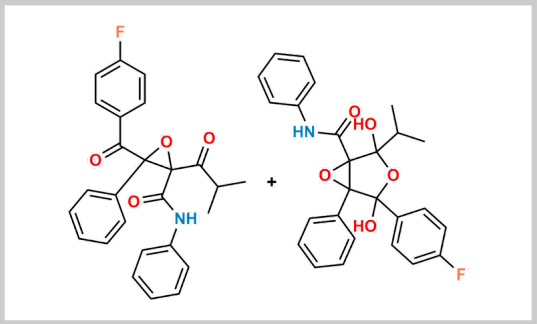
Chemical Name :
Mixture of (2E,3E)-3-(4-fluorobenzoyl)-2-(2-methylpropanoyl)-N,3-diphenyloxirane-2-carboxamide (D1) and (1E,2E,4E,5E)-4-(4-fluorophenyl)-2,4-dihydroxy-N,5-diphenyl-2-(propan-2-yl)-3,6-dioxabicyclo[3.1.0]hexane-1-carboxamide (D2) (as per EP)

CAT No. : KMA002067

CAS No. : Not Available

Molecular Formula : C26H22FNO4 : C26H24FNO5

Molecular Weight : 431.5 : 449.5



Analytical Information

Batch No. : ATS-EP-D-030-016

Description : Light Yellow Solid

HPLC Purity : 98.46 %

Weight Loss By TGA : 0.03 %

% Potency : 98.43 %

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

Mass : Confirm c

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 - 0.03(Weight Loss By TGA)] x [98.46(HPLC Purity)]/100 = 98.43 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		20/05/2026
Reviewed & Approved By	Quality Control	Jatin Patel		20/05/2026

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