

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002067-01)

Release Date: 29/11/2023

Re-test Date: 28/11/2026

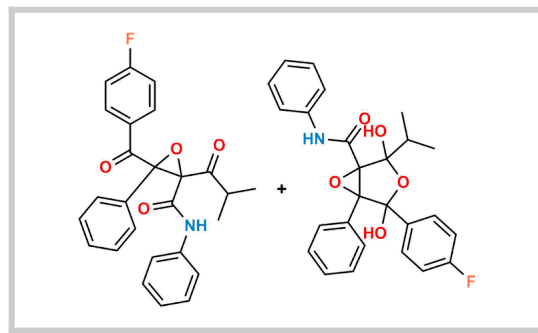
Atorvastatin EP Impurity D

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	Solubility	: THF : Buffer Sol. : ACN 5:35:60 (V/V/V)
Description	: Light Yellow Solid	Mass	: Confirm c
HPLC Purity	: 98.46 %	IR	: Confirm
Weight Loss By TGA	: 0.03 %	¹H NMR	: Confirm
% Potency	: 98.43 %		

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