

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002138-01)

Release Date: 22/03/2023

Re-test Date: 21/03/2026

Atorvastatin Pyrrolidone Lactone (USP)

Identification

Chemical Name :

5-(4-Fluorophenyl)-1-{2-[(2R,4R)-4-hydroxy-6-oxotetrahydro-2H-pyran-2-yl]ethyl}-3-isopropyl-2-oxo-N,4-diphenyl-2,3-dihydro-1H-pyrrole-3-carboxamide (as per USP)

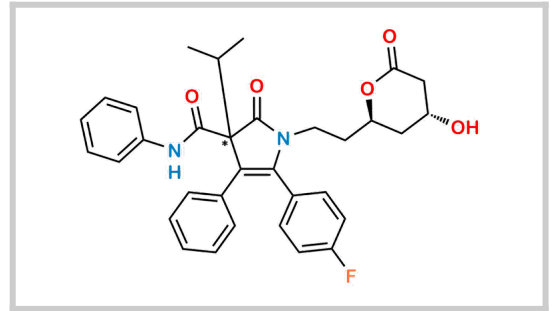
Alt. Name : Atorvastatin Lactam Lactone

CAT No. : KMA002138

CAS No. : 906552-19-0

Molecular Formula : C33H33FN2O5

Molecular Weight : 556.6



Analytical Information

Batch No. : ATS-PY-LAC-029

Solubility : DMF

Description : White Solid

Mass : Confirm

HPLC Purity : 99.59 %

IR : Confirm

Weight Loss By TGA : 0.90 %

1H NMR : Confirm

% Potency : 98.69 %

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 - 0.90(Weight Loss By TGA)] x [99.59(HPLC Purity)]/100 = 98.69 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		03/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		03/02/2025

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