

CERTIFICATE OF ANALYSIS

(Certificate No. KMA002078-01)

Release Date: 21/09/2024

Re-test Date: 20/09/2027

Atorvastatin Impurity H

Identification

Chemical Name :

(4R,6R)-6-[2-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]ethyl]-4-hydroxyoxan-2-one (as per EP); 5-(4-Fluorophenyl)-1-{2-[(2R, 4R)-4-hydroxy-6-oxotetrahydro-2H-pyran-2-yl]ethyl}-2-isopropyl-N,4-diphenyl-1H-pyrrole-3-carboxamide (as per USP)

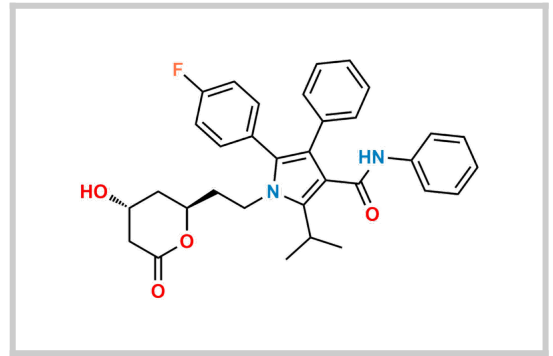
Alt. Name : Atorvastatin USP related Compound
H ; Atorvastatin lactone (USP) ;
Atorvastatin δ -lactone

CAT No. : KMA002078

CAS No. : 125995-03-1

Molecular Formula : C33H33FN2O4

Molecular Weight : 540.6



Analytical Information

Batch No. : ATS-LAC-011-120

Description : Off White Solid

HPLC Purity : 95.18 %

Weight Loss By TGA : 0.46 %

% Potency : 94.74 %

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 = $[100 - 0.46(\text{Weight Loss By TGA})] \times [95.18(\text{HPLC Purity})]/100 = 94.74 \%$
-Re-tested on 21.09.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		23/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		23/09/2024

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