

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002078-01)

Release Date: 21/09/2024

Re-test Date: 20/09/2027

## Atorvastatin Lactone

### 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)

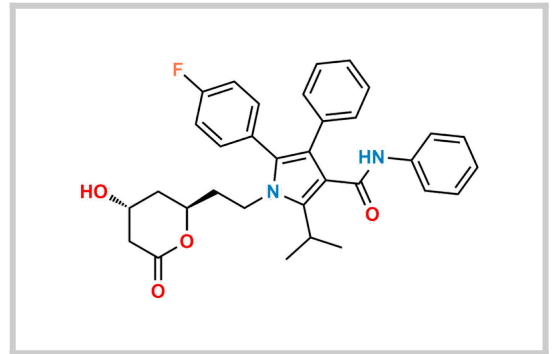
**Alt. Name** : Atorvastatin USP related Compound  
H ; Atorvastatin lactone (USP) ;  
Atorvastatin  $\delta$ -lactone

**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		04/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		04/03/2025

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