

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002137-02)

Release Date: 12/06/2025

Re-test Date: 11/06/2028

## Atorvastatin Impurity Q

### Identification

**Chemical Name :**

(3R,5R)-7-[5-(4-Fluorophenyl)-3-isopropyl-2-oxo-4-phenyl-3-(phenylcarbamoyl)-2,3-dihydro-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid Sodium salt (as per USP)

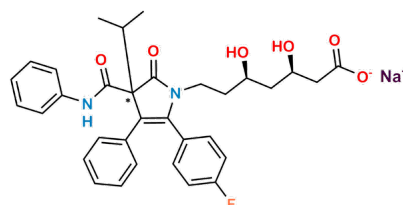
**Alt. Name** : Atorvastatin Lactam Impurity ;  
Atorvastatin Oxo Impurity

**CAT No.** : KMA002137

**CAS No.** : 148217-40-7

**Molecular Formula** : C33H34FN2O6 : Na

**Molecular Weight** : 573.6 : 23.0



### Analytical Information

**Batch No.** : A002137-102-072

**Description** : Off White Solid

**HPLC Purity** : 94.52 %

**Weight Loss By TGA** : 3.26 %

**% Potency** : 91.44 %

**Solubility** : Methanol

**Mass** : Confirm as Na adduct

**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** =  $[100 - 3.26(\text{Weight Loss By TGA})] \times [94.52(\text{HPLC Purity})]/100 = 91.44 \%$

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		19/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		19/07/2025

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