

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002137-04)

Release Date: 09/06/2026

Re-test Date: 08/06/2029

## 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)

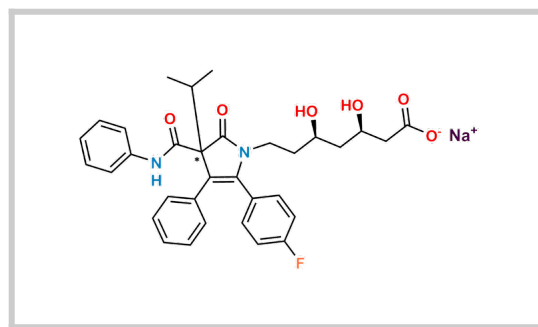
**Alt. Name** : Atorvastatin Lactam Impurity ;  
Atorvastatin Oxo Impurity

**CAT No.** : KMA002137

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

**Molecular Formula** : C<sub>33</sub>H<sub>34</sub>FN<sub>2</sub>O<sub>6</sub> : Na

**Molecular Weight** : 573.6 : 23.0



### Analytical Information

**Batch No.** : A002137-136-008

**Description** : Light Brown Solid

**HPLC Purity** : 94.27 %

**Weight Loss By TGA** : 1.69 %

**% Potency** : 92.68 %

**Solubility** : Methanol

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H 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 - 1.69(Weight Loss By TGA)] x [94.27(HPLC Purity)]/100 = 92.68 %

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		09/06/2026
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		09/06/2026

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR AND TGA