

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002066-01)

Release Date: 06/03/2025

Re-test Date: 05/03/2028

## ATORVASTATIN RELATED COMPOUND C

### Identification

**Chemical Name :**

(3R,5R)-7-[2,3-bis(4-fluorophenyl)-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid Sodium salt (as per EP); Sodium (3R,5R)-7-[2,3-Bis(4-fluorophenyl)-5-isopropyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoate (as per USP)

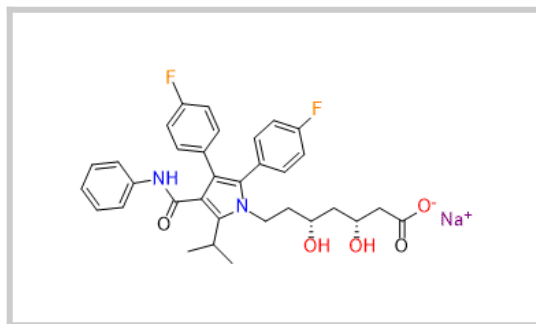
**Alt. Name** : Atorvastatin USP Related Compound C ; fluoroatorvastatin (EP)

**CAT No.** : KMA002066

**CAS No.** : 1807481-00-0

**Molecular Formula** : C<sub>33</sub>H<sub>34</sub>F<sub>2</sub>N<sub>2</sub>O<sub>5</sub> : Na

**Molecular Weight** : 576.6 : 23.0



### Analytical Information

**Batch No.** : A002066-091-245

**Description** : Light Yellow Solid

**HPLC Purity** : 96.06 %

**Weight Loss By TGA** : 0.89 %

**% Potency** : 95.21 %

**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 - 0.89(Weight Loss By TGA)] x [96.06(HPLC Purity)]/100 = 95.21 %

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		02/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		02/05/2025

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, IR and TGA