

# **CERTIFICATE OF ANALYSIS**

(Certificate No. KMA002001-01)

**Release Date:** 30/11/2023

**Re-test Date:** 29/11/2026

## **Atorvastatin Impurity A**

### **Identification**

**Chemical Name :**

(3R,5R)-7-[3-(Phenylcarbamoyl)-5-phenyl-2-isopropyl-4-phenyl-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid calcium

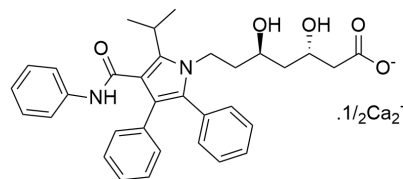
**Alt. Name** : Desfluoro Atorvastatin Calcium

**CAT No.** : KMA002001

**CAS No.** : 433289-83-9

**Molecular Formula** : C<sub>33</sub>H<sub>35</sub>N<sub>2</sub>O<sub>5</sub>: 1/2Ca

**Molecular Weight** : 539.63 : 1/2(40.1)



### **Analytical Information**

**Batch No.** : ATS-IMP-A-182

**Description** : Off White Solid

**HPLC Purity** : 97.02 %

**Weight Loss By TGA** : 2.21 %

**% Potency** : 94.88 %

**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 - 2.21(Weight Loss By TGA)] x [97.02(HPLC Purity)]/100 = 94.88 %

Remarks : COA regenerated on 12.09.2024

-Re-tested on 30.11.2023

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/05/2025

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