

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002088-01)

Release Date: 10/02/2025

Re-test Date: 09/02/2028

## Atorvastatin AVE Ketal Impurity

### Identification

**Chemical Name :**

[(4R,6R)-6-[2-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]ethyl]-2,2-dimethyl-1,3-dioxan-4-yl]acetic acid (as per EP)

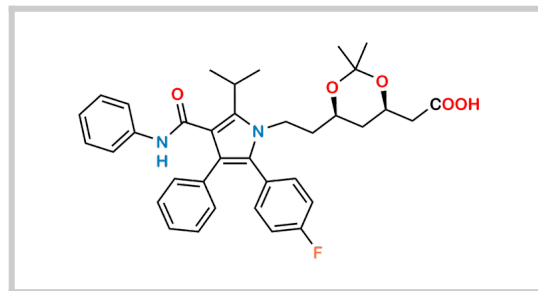
**Alt. Name** : Atorvastatin Acetonide

**CAT No.** : KMA002088

**CAS No.** : 581772-29-4

**Molecular Formula** : C<sub>36</sub>H<sub>39</sub>FN<sub>2</sub>O<sub>5</sub>

**Molecular Weight** : 598.7



### Analytical Information

**Batch No.** : ATS-APDACID-019-058

**Description** : Off White Solid

**HPLC Purity** : 95.51 %

**Weight Loss By TGA** : 2.58 %

**% Potency** : 93.05 %

**Solubility** : Acetonitrile

**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 - 2.58(Weight Loss By TGA)] x [95.51(HPLC Purity)]/100 = 93.05 %  
-Re-tested on 10.02.2025.

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		17/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		17/03/2025

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