

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA002011-01)

Release Date: 22/02/2023

Re-test Date: 21/02/2026

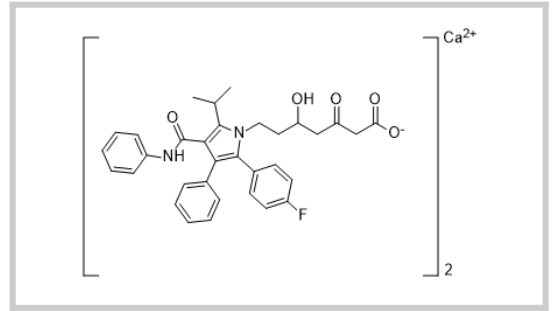
## rac-3-Oxo atorvastatin Calcium

### Identification

**Chemical Name :**

2-(4-Fluorophenyl)-delta-hydroxy-5-(1-methylethyl)-beta-oxo-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic Acid Calcium Salt

CAT No. : KMA002011  
CAS No. : 1391052-00-8  
Molecular Formula : C33H32FN2CaO5  
Molecular Weight : 556.62 (M-Ca)



### Analytical Information

|                    |                                |            |           |
|--------------------|--------------------------------|------------|-----------|
| Batch No.          | : ATS-PY-045-068               | Solubility | : DMF     |
| Description        | : Off white crystalline powder | Mass       | : Confirm |
| HPLC Purity        | : 97.58 %                      | IR         | : Confirm |
| Weight Loss By TGA | : 2.90 %                       | 1H NMR     | : Confirm |
| % Potency          | : 94.75 %                      |            |           |

### 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 =  $[100 - 2.90(\text{Weight Loss By TGA})] \times [97.58(\text{HPLC Purity})]/100 = 94.75 \%$   
Recommendation : Released

|                        | Department      | Name          | Signature | Date       |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By            | Analytical      | Jignesh Patel |           | 14/06/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel   |           | 14/06/2024 |

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