









Registered Address: Chemicea Pharmaceuticals Pvt Ltd, Platinum Springs,

Unit No- A- 205&206 Second floor, Plot No: G-6, G-20 to G 24, Taloja- MIDC, Opp. Dena Bank

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### **CERTIFICATE OF ANALYSIS**

Analysis Date: Dec 2022 Re-test Date: Nov 2025

#### **Product Name: Atorvastatin EP Impurity I**

### **Identification:**

Chemical Name: tert-butyl [(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]acetate (as per EP)

Synonyms : Atorvastatin USP Related

Compound I; Acetonide

Atorvastatin (USP); Atorvastatin

Acetonide t-Butyl Ester

CAS Number : 125971-95-1

CAT Number : CP-A32009

Molecular Formula : C40H47FN2O5

Molecular Weight : 654.81

Batch Number : CHEM-ATO-I

Storage Condition : Tightly closed, Inert atmosphere at 2 to 8° C

Shipping condition : All Products are stable to be shipped at room temperature, if specific condition required it is

mention in the COA

## **Analytical Information:**

| Sr. No. | Test           | Result                   |
|---------|----------------|--------------------------|
| 1)      | Description    | White Solid              |
| 2)      | Solubility     | Soluble in Methanol/DMSO |
| 3)      | MASS By LCMS   | Confirm to structure     |
| 4)      | Purity By HPLC | 99.64%                   |
| 5)      | H1NMR          | Confirm to structure     |
| 6)      | 13CNMR         | Confirm to structure     |



# **Prepared and Reviewed By**

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Ms Priyanka Salunkhe (Manager QC Analytical)

### **Approved By**



Ms Rohini Gagare (QA Head)

| Note: Product supplied by Chemicea are for R&D purpose only and not for human consumptions. |  |  |  |  |
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