

# CERTIFICATE OF ANALYSIS

(Certificate No. KMS001007-01)

Release Date: 24/07/2024

Re-test Date: 23/07/2027

## Simvastatin Impurity B

### Identification

**Chemical Name :**

(1S,3R,7S,8S,8aR)-8-[2-[(2R,4R)-4-(acetyloxy)-6-oxotetrahydro-2H-pyran-2-yl]ethyl]-3,7-dimethyl-1,2,3,7,8,8a-hexahydronaphthalen-1-yl 2,2-dimethylbutanoate

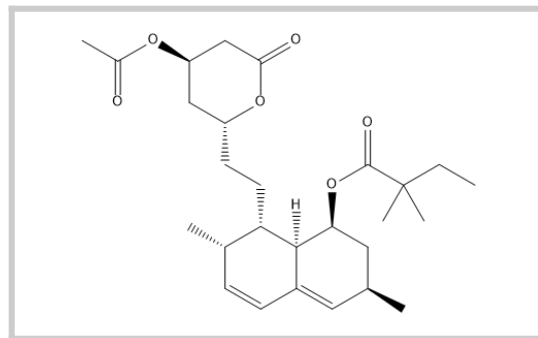
**Alt. Name** : Simvastatin USP Related Compound B ; Simvastatin Acetate Ester

**CAT No.** : KMS001007

**CAS No.** : 145576-25-6

**Molecular Formula** : C<sub>27</sub>H<sub>40</sub>O<sub>6</sub>

**Molecular Weight** : 460.60



### Analytical Information

**Batch No.** : SIM-EPB-09-095

**Description** : White Solid

**HPLC Purity** : 95.31 %

**Weight Loss By TGA** : 0.89 %

**% Potency** : 94.46 %

**Solubility** : Acetonitrile

**Mass** : Confirm as water adduct

**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 [95.31(HPLC Purity)]/100 = 94.46 %  
-Re-tested on 24.07.2024

**Recommendation** : Released

|                        | Department      | Name          | Signature | Date       |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By            | Analytical      | Jignesh Patel |           | 27/05/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel   |           | 27/05/2025 |

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