

# CERTIFICATE OF ANALYSIS

(Certificate No. KMS001007-02)

Release Date: 28/05/2026

Re-test Date: 27/05/2029

## 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

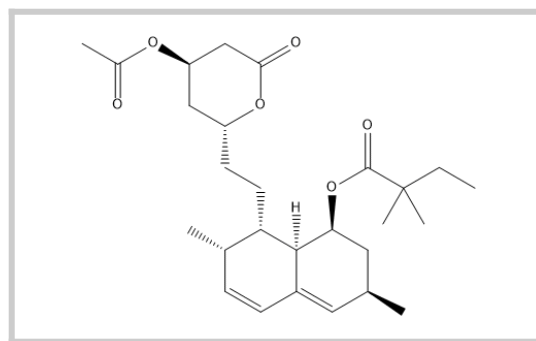
**Alt. Name** : Simvastatin USP Related Compound B ; Simvastatin Acetate Ester

**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.** : S001007-114-357

**Description** : Off White Solid

**HPLC Purity** : 97.89 %

**Weight Loss By TGA** : 0.05 %

**% Potency** : 97.84 %

**Solubility** : ACN

**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 - 0.05(Weight Loss By TGA)] x [97.89(HPLC Purity)]/100 = 97.84 %

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/05/2026
Reviewed & Approved By	Quality Control	Jatin Patel		28/05/2026

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