

# CERTIFICATE OF ANALYSIS

(Certificate No. KMS001008-02)

Release Date: 11/10/2025

Re-test Date: 10/10/2028

## Simvastatin Impurity C

### Identification

**Chemical Name :**

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

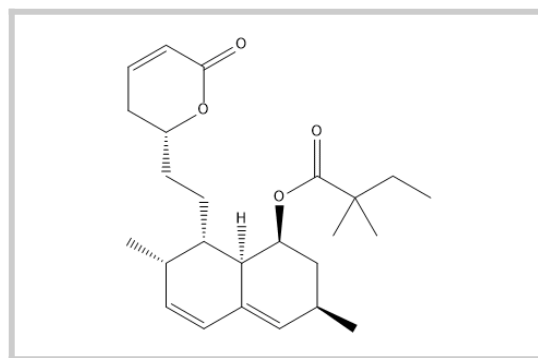
**Alt. Name** : Simvastatin USP Related Compound C ; 2,3-Anhydro Simvastatin ; Dehydro Simvastatin

**CAT No.** : KMS001008

**CAS No.** : 210980-68-0

**Molecular Formula** : C<sub>25</sub>H<sub>36</sub>O<sub>4</sub>

**Molecular Weight** : 400.55



### Analytical Information

**Batch No.** : S001008-102-066

**Description** : Light Yellow Syrup

**HPLC Purity** : 97.84 %

**Weight Loss By TGA** : 2.77 %

**% Potency** : 95.13 %

**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 - 2.77(Weight Loss By TGA)] x [97.84(HPLC Purity)]/100 = 95.13 %

-Re-purified and re-tested on 11.10.2025

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		10/12/2025
Reviewed & Approved By	Quality Control	Jatin Patel		10/12/2025

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