

# CERTIFICATE OF ANALYSIS

(Certificate No. KMS001008-01)

Release Date: 23/07/2024

Re-test Date: 22/07/2027

## Simvastatin EP 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

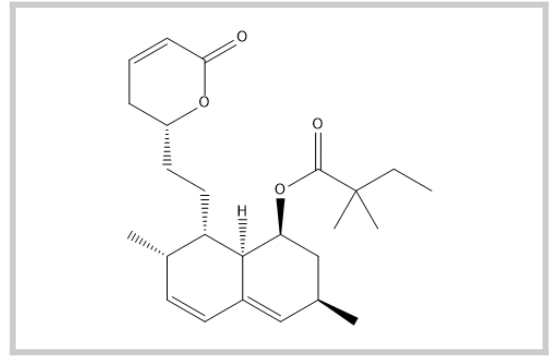
**Alt. Name** : Simvastatin USP Related Compound C ; 2,3-Anhydro Simvastatin ; Dehydro Simvastatin

**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.** : SIM-EP-IMP-C-019-304

**Description** : Light Yellow Syrup

**HPLC Purity** : 97.71 %

**Weight Loss By TGA** : 2.80 %

**% Potency** : 94.97 %

**Solubility** : ACN

**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** =  $[100 - 2.80(\text{Weight Loss By TGA})] \times [97.71(\text{HPLC Purity})]/100 = 94.97 \%$

-Re-tested on 23.07.2024

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		24/07/2024
Reviewed & Approved By	Quality Control	Jatin Patel		24/07/2024

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