

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

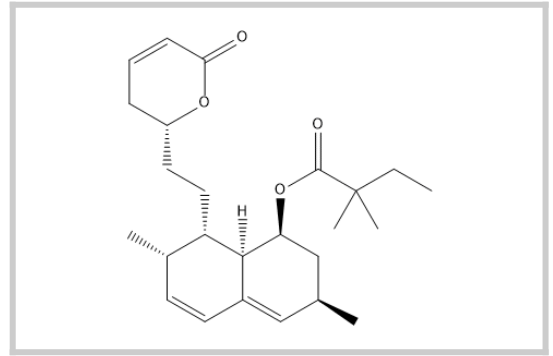
Alt. Name : Simvastatin USP Related Compound C ; 2,3-Anhydro Simvastatin ; Dehydro Simvastatin

CAT No. : KMS001008

CAS No. : 210980-68-0

Molecular Formula : C₂₅H₃₆O₄

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

¹H 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, ¹H NMR, IR and TGA