

CERTIFICATE OF ANALYSIS

(Certificate No. KMS001008-02)

Release Date: 09/10/2025

Re-test Date: 08/10/2028

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

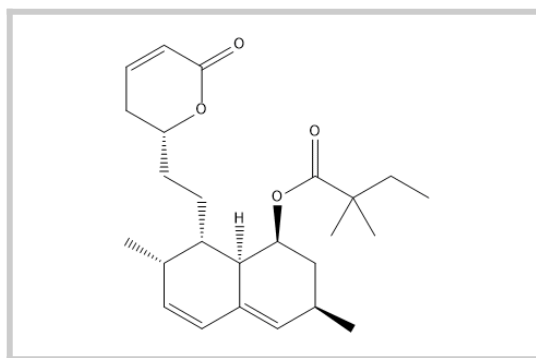
Alt. Name : Simvastatin USP Related Compound C ; 2,3-Anhydro Simvastatin ; Dehydro Simvastatin

CAT No. : KMS001008

CAS No. : 210980-68-0

Molecular Formula : C₂₅H₃₆O₄

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

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

-Re-purified and re-tested on 09.10.2025

Recommendation : Released

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

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA