

CERTIFICATE OF ANALYSIS

(Certificate No. KMS001004-01)

Release Date: 30/03/2024

Re-test Date: 29/03/2027

Simvastatin Impurity E

Identification

Chemical Name :

(S)-(1S,3R,7S,8S,8aR)-8-(2-((2R,4R)-4-hydroxy-6-oxotetrahydro-2H-pyran-2-yl)ethyl)-3,7-dimethyl-1,2,3,7,8,8a-hexahydronaphthalen-1-yl 2-methylbutanoate

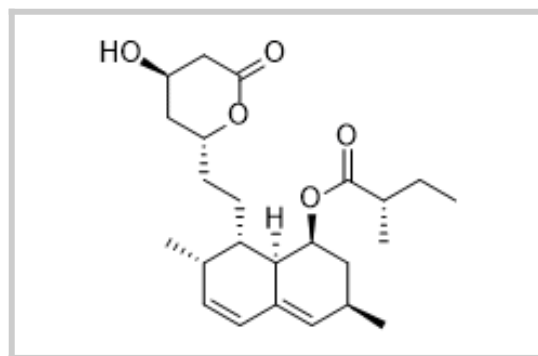
Alt. Name : Simvastatin USP Related Compound E ; Lovastatin ; Desmethyl Simvastatin

CAT No. : KMS001004

CAS No. : 75330-75-5

Molecular Formula : C₂₄H₃₆O₅

Molecular Weight : 404.54



Analytical Information

Batch No. : LOVA-RS-019-111

Solubility : Methanol

Description : White Solid

Mass : Confirm

HPLC Purity : 97.47 %

IR : Confirm

Weight Loss By TGA : 0.47 %

¹H NMR : Confirm

% Potency : 97.01 %

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 - 0.47(Weight Loss By TGA)] x [97.47(HPLC Purity)]/100 = 97.01 %
-Re-tested on 30.03.2024

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 27/05/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 27/05/2025 |

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