

CERTIFICATE OF ANALYSIS

(Certificate No. KMS00102-02)

Release Date: 01/05/2025

Re-test Date: 30/04/2028

Simvastatin Methyl Ester Impurity

Identification

Chemical Name :

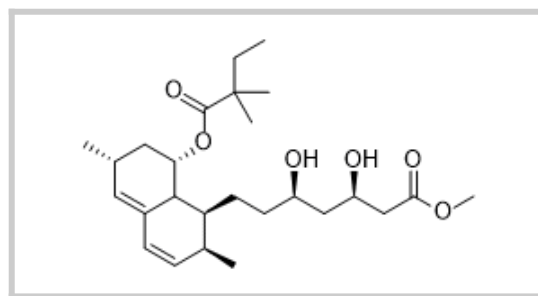
(3R,5R)-methyl 7-((1S,2S,6R,8S)-8-((2,2-dimethylbutanoyl)oxy)-2,6-dimethyl-1,2,6,7,8,8a-hexahydronaphthalen-1-yl)-3,5-dihydroxyheptanoate

CAT No. : KMS00102

CAS No. : 145576-26-7

Molecular Formula : C₂₆H₄₂O₆

Molecular Weight : 450.61



Analytical Information

Batch No. : S00102-102-007

Description : Colourless Syrup

HPLC Purity : 98.01 %

Weight Loss By TGA : 1.28 %

% Potency : 96.76 %

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 - 1.28(Weight Loss By TGA)] x [98.01(HPLC Purity)]/100 = 96.76 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|-------------|-----------|------------|
| Prepared By | Analytical | Parag Patel | | 01/05/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 01/05/2025 |

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