

CERTIFICATE OF ANALYSIS

(Certificate No. KMS00102-01)

Release Date: 10/04/2024

Re-test Date: 09/04/2027

Simvastatin Methyl Ester Impurity

Identification

Chemical Name :

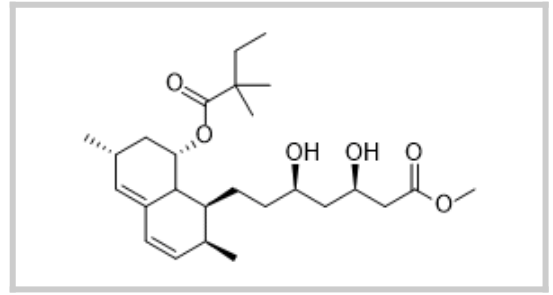
(3R,5R)-methyl 7-((1S,2S,6R,8S)-8-((2,2-dimethylbutanoyl)oxy)-2,6-dimethyl-1,2,6,7,8,8a-hexahydronaphthalen-1-yl)-3,5-dihydroxyheptanoate

CAT No. : KMS00102

CAS No. : 145576-26-7

Molecular Formula : C₂₆H₄₂O₆

Molecular Weight : 450.61



Analytical Information

Batch No. : SIM-ME-019-349

Description : Colourless Syrup

HPLC Purity : 96.40 %

Weight Loss By TGA : 3.25 %

% Potency : 93.27 %

Solubility : ACN

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 = $[100 - 3.25(\text{Weight Loss By TGA})] \times [96.40(\text{HPLC Purity})]/100 = 93.27 \%$
-Re-tested on 10.04.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		10/04/2024
Reviewed & Approved By	Quality Control	Jatin Patel		10/04/2024

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA