

CERTIFICATE OF ANALYSIS

(Certificate No. KMS001006-01)

Release Date: 20/04/2024

Re-test Date: 19/04/2027

Simvastatin Impurity K

Identification

Chemical Name :

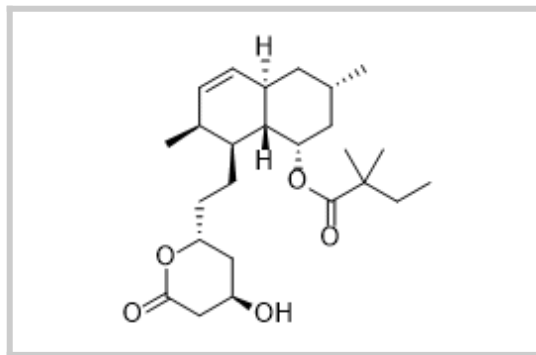
(1S,3S,4aR,7S,8S,8aS)-8-(2-((2R,4R)-4-hydroxy-6-oxotetrahydro-2H-pyran-2-yl)ethyl)-3,7-dimethyl-1,2,3,4,4a,7,8,8a-octahydronaphthalen-1-yl 2,2-dimethylbutanoate

CAT No. : KMS001006

CAS No. : Not Available

Molecular Formula : C₂₅H₄₀O₅

Molecular Weight : 420.58



Analytical Information

Batch No. : SIM-IMP-EPK-019-095

Description : Colourless Thick Syrup

HPLC Purity : 99.84 %

Weight Loss By TGA : 1.72 %

% Potency : 98.12 %

Solubility : Methanol

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 = $[100 - 1.72(\text{Weight Loss By TGA})] \times [99.84(\text{HPLC Purity})]/100 = 98.12 \%$

-Remarks : Re-purified and Re-tested on 20.04.2024

-COA Re-generated on 24.04.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		24/04/2024
Reviewed & Approved By	Quality Control	Jatin Patel		24/04/2024

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