CERTIFICATE OF ANALYSIS

(Certificate No. KMS001006-01)

Release Date: 20/04/2024 **Re-test Date:** 19/04/2027

Simvastatin Impurity K

Identification

Chemical Name:

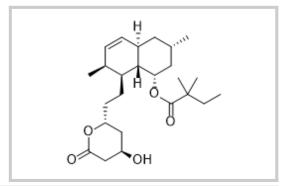
(1S,3S,4aR,7S,8S,8aS)-8-(2-((2R,4R)-4-hydroxy-6-oxotetrahydro-2H-pyran-2-yl)ethyl)-3,7-dimethyl-1,2,3,4,4a,7,8,8a-octahydronaphthalen-1-yl 2,2-dimethylbutanoate

CAT No. : KMS001006

CAS No. : Not Available

Molecular Formula : C25H40O5

Molecular Weight : 420.58



Analytical Information

: SIM-IMP-EPK-019-095 **Solubility** Batch No. : Methanol **Description** : Colourless Thick Syrup Mass : Confirm **HPLC Purity** : 99.84 % IR : Confirm Weight Loss By TGA : 1.72 % : Confirm 1H NMR

% Potency : 98.12 %

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(Weight Loss By TGA)] x [99.84(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, 1HNMR, IR and TGA