

CERTIFICATE OF ANALYSIS

(Certificate No. KMS001006-01)

Release Date: 14/04/2026

Re-test Date: 13/04/2029

SIMVASTATIN EP IMPURITY K

Identification

Chemical Name :

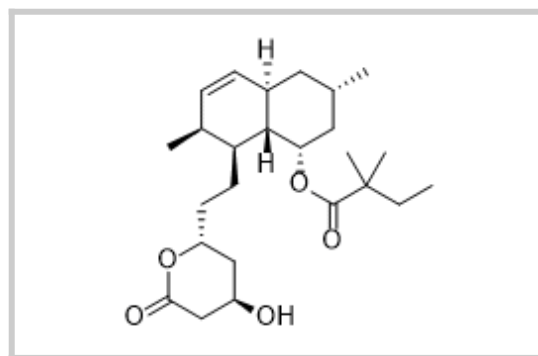
(1S,3S,4aR,7S,8S,8aS)-8-(2-((2R,4R)-4-hydroxy-6-oxotetrahydro-2H-pyran-2-yl)ethyl)-3,7-dimethyl-1,2,3,4,4a,7,8,8a-octahydronaphthalen-1-yl 2,2-dimethylbutanoate

CAT No. : KMS001006

CAS No. : Not Available

Molecular Formula : C₂₅H₄₀O₅

Molecular Weight : 420.58



Analytical Information

Batch No. : S001006-114-255

Description : Colourless Thick Syrup

HPLC Purity : 98.90 %

Weight Loss By TGA : 0.62 %

% Potency : 98.29 %

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 = $[100 - 0.62(\text{Weight Loss By TGA})] \times [98.90(\text{HPLC Purity})]/100 = 98.29 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		14/04/2026
Reviewed & Approved By	Quality Control	Parag Vekariya		14/04/2026

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