

CERTIFICATE OF ANALYSIS

(Certificate No. KMS001009-01)

Release Date: 23/07/2024

Re-test Date: 22/07/2027

Simvastatin EP Impurity G

Identification

Chemical Name :

(1S,3R,7S,8S,8aR)-8-[2-[(2R,4R)-4-Hydroxy-6-oxotetrahydro-2H-pyran-2-yl]ethyl]-3,7-dimethyl-1,2,3,7,8,8a-hexahydronaphthalen-1-yl 2,2-dimethylbut-3-enoate

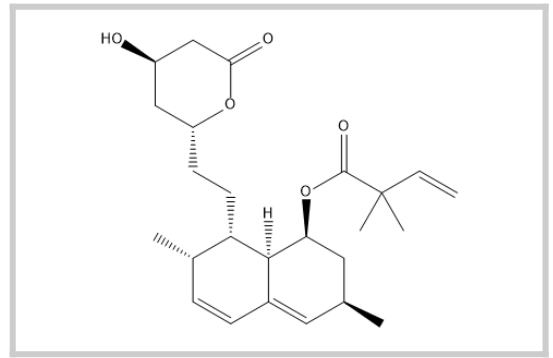
Alt. Name : Simvastatin USP Related Compound G ; Simvastatin-3-en ; Methylene simvastatin

CAT No. : KMS001009

CAS No. : 1449248-72-9

Molecular Formula : C₂₅H₃₆O₅

Molecular Weight : 416.55



Analytical Information

Batch No. : SIM-EP-IMP-G-030-102

Description : Off White Solid

HPLC Purity : 97.98 %

Weight Loss By TGA : 0.70 %

% Potency : 97.29 %

Solubility : ACN

Mass : Confirm as Sodium adduct

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 - 0.70(Weight Loss By TGA)] x [97.98(HPLC Purity)]/100 = 97.29 %

-Re-tested on 23.07.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		24/07/2024
Reviewed & Approved By	Quality Control	Jatin Patel		24/07/2024

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