CERTIFICATE OF ANALYSIS

(Certificate No. KMS001009-01)

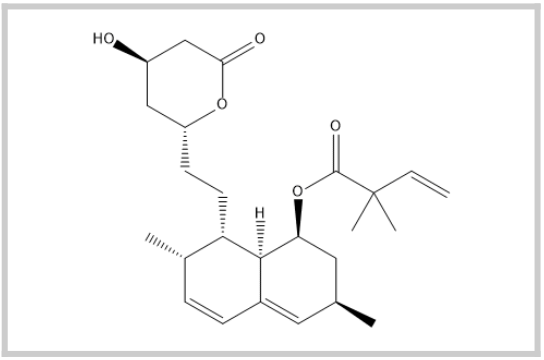
Release Date: 23/07/2024 **Re-test Date:** 22/07/2027

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	**Solubility**	: ACN
Description	: Off White Solid	**Mass**	: Confirm as Sodium adduct
HPLC Purity	: 97.98 %	**IR**	: Confirm
Weight Loss By TGA	: 0.70 %	**1H NMR**	: Confirm
% Potency	: 97.29 %		

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, 1HNMR, IR and TGA