CERTIFICATE OF ANALYSIS

(Certificate No. KMS001004-01)

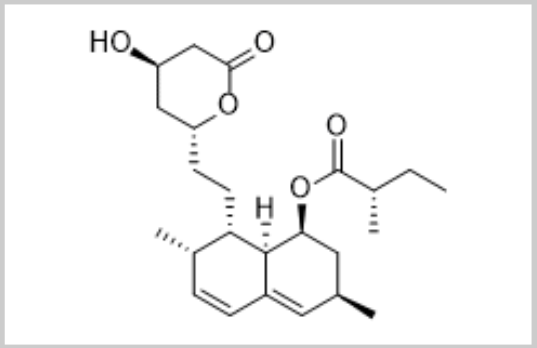
Release Date: 30/03/2024 **Re-test Date:** 29/03/2027

Simvastatin Impurity E

Identification

Chemical Name :
(S)-(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-methylbutanoate

Alt. Name	: Simvastatin USP Related Compound E ; Lovastatin ; Desmethyl Simvastatin
CAT No.	: KMS001004
CAS No.	: 75330-75-5
Molecular Formula	: C24H36O5
Molecular Weight	: 404.54



Analytical Information

Batch No.	: LOVA-RS-019-111	**Solubility**	: Methanol
Description	: White Solid	**Mass**	: Confirm
HPLC Purity	: 97.47 %	**IR**	: Confirm
Weight Loss By TGA	: 0.47 %	**1H NMR**	: Confirm
% Potency	: 97.01 %		

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 - 0.47(Weight Loss By TGA)] x [97.47(HPLC Purity)]/100 = 97.01 %
-Re-tested on 30.03.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		27/05/2025

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA