CERTIFICATE OF ANALYSIS

(Certificate No. KMS001005-01)

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

Simvastatin Impurity F

Identification

Chemical Name :
(R)-(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

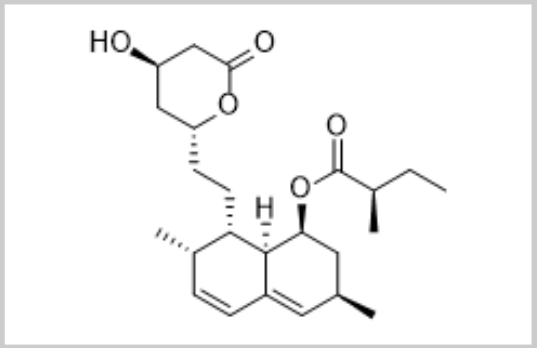
Alt. Name : Simvastatin USP Related Compound F; epi-Lovastatin ; Lovastatin epimer

CAT No. : KMS001005

CAS No. : 79952-44-6

Molecular Formula : C24H36O5

Molecular Weight : 404.54



Analytical Information

Batch No.	: SIM-EP-IMP-F-030-101	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 97.45 %	**IR**	: Confirm
Weight Loss By TGA	: 0.60 %	**1H NMR**	: Confirm
% Potency	: 96.87 %		

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 - 0.60(Weight Loss By TGA)] x [97.45(HPLC Purity)]/100 = 96.87 %
-Re-tested on 30.03.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		30/04/2025
Reviewed & Approved By	Quality Control	Jatin Patel		30/04/2025

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