CERTIFICATE OF ANALYSIS

(Certificate No. KMS001010-01)

Release Date: 24/07/2024 **Re-test Date:** 23/07/2027

Simvastatin EP Impurity I

Identification

Chemical Name :
(1S,3R,7S,8S)-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 isobutyrate

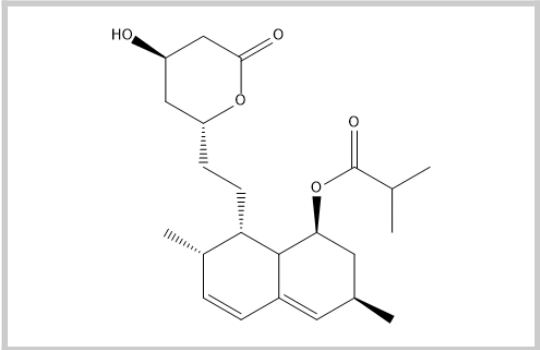
Alt. Name : 2

CAT No. : KMS001010

CAS No. : 79902-42-4

Molecular Formula : C23H34O5

Molecular Weight : 390.51



Analytical Information

Batch No.	: SIM-IMP-EPI-019-119	**Solubility**	: ACN
Description	: Off White Semi Solid	**Mass**	: Confirm
HPLC Purity	: 97.63 %	**IR**	: Confirm
Weight Loss By TGA	: 0.93 %	**1H NMR**	: Confirm
% Potency	: 96.72 %		

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 - 0.93(Weight Loss By TGA)] x [97.63(HPLC Purity)]/100 = 96.72 %
-Re-tested on 24.07.2024

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