

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

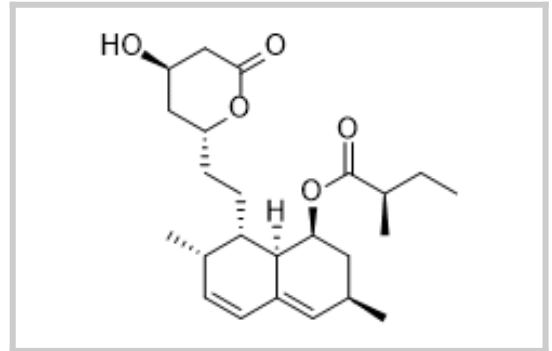
Alt. Name : Simvastatin USP Related Compound F; epi-Lovastatin ; Lovastatin epimer

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

Description : Off White Solid

HPLC Purity : 97.45 %

Weight Loss By TGA : 0.60 %

% Potency : 96.87 %

Solubility : ACN

Mass : Confirm

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 - 0.60(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	Jignesh Patel		08/04/2024
Reviewed & Approved By	Quality Control	Jatin Patel		08/04/2024

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