

CERTIFICATE OF ANALYSIS

(Certificate No. KMS001007-01)

Release Date: 24/07/2024

Re-test Date: 23/07/2027

Simvastatin EP Impurity B

Identification

Chemical Name :

(1S,3R,7S,8S,8aR)-8-[2-[(2R,4R)-4-(acetyloxy)-6-oxotetrahydro-2H-pyran-2-yl]ethyl]-3,7-dimethyl-1,2,3,7,8,8a-hexahydronaphthalen-1-yl 2,2-dimethylbutanoate

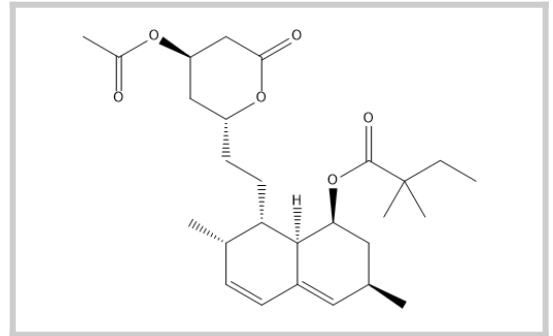
Alt. Name : Simvastatin USP Related Compound B ; Simvastatin Acetate Ester

CAT No. : KMS001007

CAS No. : 145576-25-6

Molecular Formula : C₂₇H₄₀O₆

Molecular Weight : 460.60



Analytical Information

Batch No. : SIM-EPB-09-095

Description : White Solid

HPLC Purity : 95.31 %

Weight Loss By TGA : 0.89 %

% Potency : 94.46 %

Solubility : ACN

Mass : Confirm as water adduct

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 - 0.89(Weight Loss By TGA)] x [95.31(HPLC Purity)]/100 = 94.46 %
-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