

CERTIFICATE OF ANALYSIS

(Certificate No. KMS001001-01)

Release Date: 05/02/2024

Re-test Date: 04/02/2027

Simvastatin Impurity J

Identification

Chemical Name :

(1S,3R,7S,8S,8aR)-8-[2-[(2R,4R)-4-methoxy-6-oxooxan-2-yl]ethyl]-3,7-dimethyl-1,2,3,7,8,8a-hexahydronaphthalen-1-yl 2,2-dimethylbutanoate

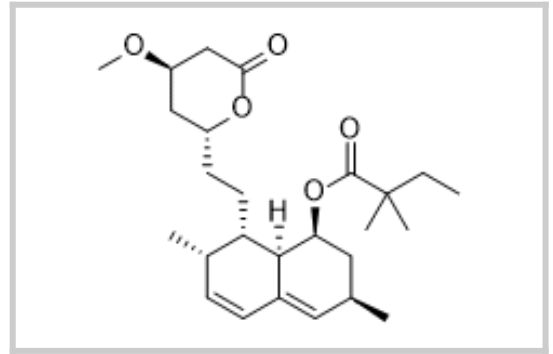
Alt. Name : Simvastatin 4

CAT No. : KMS001001

CAS No. : 864357-88-0

Molecular Formula : C₂₆H₄₀O₅

Molecular Weight : 432.59



Analytical Information

Batch No. : SIM-IMP-EPJ-019-102

Description : Yellow Liquid

HPLC Purity : 98.30 % *

Weight Loss By TGA : 0.75 % *

% Potency : 97.56 %

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 - 0.75(Weight Loss By TGA)] x [98.30(HPLC Purity)]/100 = 97.56 %

* Re-tested on 05/02/2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		
Reviewed & Approved By	Quality Control	Jatin Patel		

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA