CERTIFICATE OF ANALYSIS

(Certificate No. KMS001001-02)

Release Date: 15/10/2026 **Re-test Date:** 14/10/2029

Simvastatin EP 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

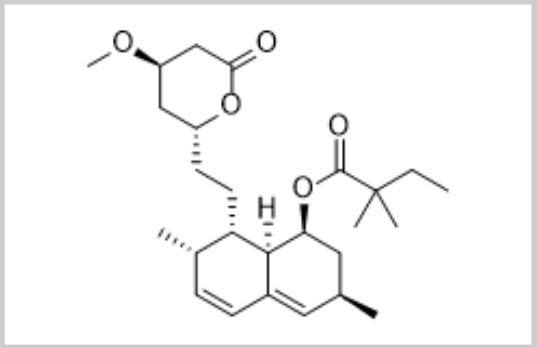
Alt. Name : Simvastatin 4

CAT No. : KMS001001

CAS No. : 864357-88-0

Molecular Formula : C26H40O5

Molecular Weight : 432.59



Analytical Information

Batch No.	: S001001-136-290	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 99.27 %	**IR**	: Confirm
Weight Loss By TGA	: 0.23 %	**1H NMR**	: Confirm
% Potency	: 99.04 %		

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 - 0.23(Weight Loss By TGA)] x [99.27(HPLC Purity)]/100 = 99.04 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		15/10/2026
Reviewed & Approved By	Quality Control	Jatin Patel		15/10/2026

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