CERTIFICATE OF ANALYSIS

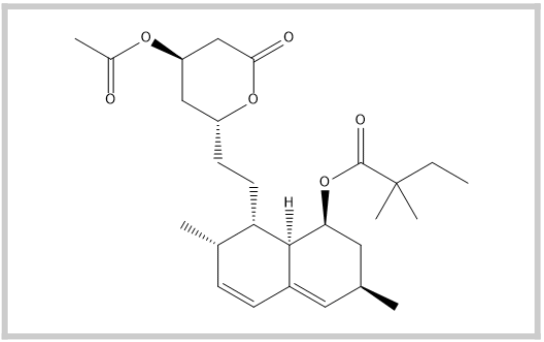
(Certificate No. KMS001007-02)

Release Date: 28/05/2026 **Re-test Date:** 27/05/2029

SIMVASTATIN 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.	: S001007-114-357	**Solubility**	: ACN
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 97.89 %	**IR**	: Confirm
Weight Loss By TGA	: 0.05 %	**1H NMR**	: Confirm
% Potency	: 97.84 %		

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 - 0.05(Weight Loss By TGA)] x [97.89(HPLC Purity)]/100 = 97.84 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/05/2026
Reviewed & Approved By	Quality Control	Jatin Patel		28/05/2026

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