CERTIFICATE OF ANALYSIS

(Certificate No. KMS001008-02)

Release Date: 09/06/2025

Re-test Date: 08/06/2028

Simvastatin Impurity C

Identification

Chemical Name :

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

Alt. Name	: Simvastatin USP Related Compound C ; 2,3-Anhydro Simvastatin ; Dehydro Simvastatin	
CAT No.	: KMS001008	
CAS No.	: 210980-68-0	
Molecular Formula	: C25H36O4	
Molecular Weight	: 400.55	

Analytical Information

Batch No.	: S001008-102-066	Solubility	: Acetonitrile
Description	: Light Yellow Syrup	Mass	: Confirm
HPLC Purity	: 98.18 %	IR	: Confirm
Weight Loss By TGA	: 2.69 %	1H NMR	: Confirm
% Potency	: 95.54 %		

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 - 2.69(Weight Loss By TGA)] x [98.18(HPLC Purity)]/100 = 95.54 %				
Recommendation	: Released			

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		09/06/2025
Reviewed & Approved By	Quality Control	Jatin Patel		09/06/2025

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