

CERTIFICATE OF ANALYSIS

(Certificate No. KMS001003-01)

Release Date: 08/04/2024

Re-test Date: 07/04/2027

Simvastatin Impurity A

Identification

Chemical Name :

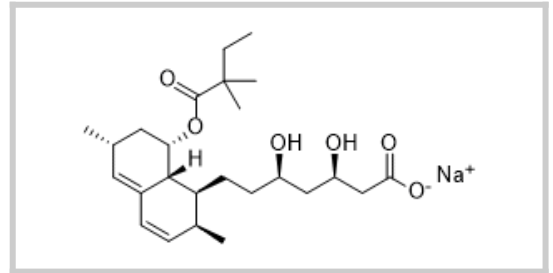
sodium (3R,5R)-7-((1S,2S,6R,8S,8aR)-8-((2,2-dimethylbutanoyl)oxy)-2,6-dimethyl-1,2,6,7,8,8a-hexahydronaphthalen-1-yl)-3,5-dihydroxyheptanoate

CAT No. : KMS001003

CAS No. : 101314-97-0(Na salt),121009-77-6(free base)

Molecular Formula : C₂₅H₄₀O₆

Molecular Weight : 436.58



Analytical Information

Batch No. : SIM-EPA-073-161

Description : Off White Solid

HPLC Purity : 98.59 %

Weight Loss By TGA : 3.29 %

% Potency : 95.35 %

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 - 3.29(Weight Loss By TGA)] x [98.59(HPLC Purity)]/100 = 95.35 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		08/04/2024
Reviewed & Approved By	Quality Control	Jatin Patel		08/04/2024

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