CERTIFICATE OF ANALYSIS

(Certificate No. KML001002-01)

Release Date: 11/03/2024 **Re-test Date:** 10/03/2027

Lovastatin Hydroxy Acid

Identification

Chemical Name :
7-[2,6-dimethyl-8-(2-methylbutanoyloxy)-1,2,6,7,8,8a-hexahydronaphthalen-1-yl]-3,5-dihydroxyheptanoate sodium Salt

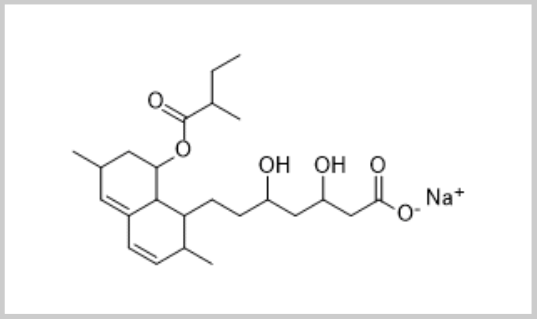
Alt. Name : Lovastatin EP impurity B

CAT No. : KML001002

CAS No. : 75225-50-2 (Na salt); 75225-51-3 (Free acid)

Molecular Formula : C24H37O6 : Na

Molecular Weight : 422.5 (Free Acid) 444.54 (Na salt)



Analytical Information

Batch No. : LOV-HY-ACID-073-118

Description : Off white solid

HPLC Purity : 96.36 %

Weight Loss By TGA : 0.91 %

% Potency : 95.48 %

Solubility : Water

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 - 0.91(Weight Loss By TGA)] x [96.36(HPLC Purity)]/100 = 95.48 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		11/03/2024
Reviewed & Approved By	Quality Control	Jatin Patel		11/03/2024

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