

# 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

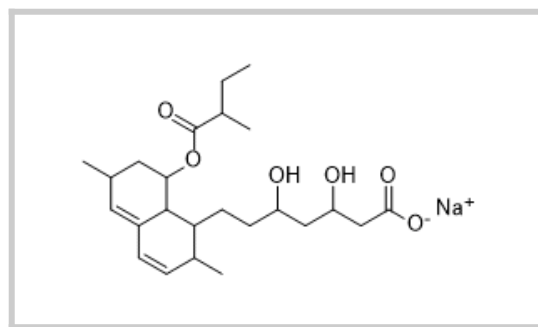
**Alt. Name** : Lovastatin EP impurity B

**CAT No.** : KML001002

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

**Molecular Formula** : C<sub>24</sub>H<sub>37</sub>O<sub>6</sub> : Na

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



### Analytical Information

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

**Solubility** : Water

**Description** : Off white solid

**Mass** : Confirm

**HPLC Purity** : 96.36 %

**IR** : Confirm

**Weight Loss By TGA** : 0.91 %

**<sup>1</sup>H NMR** : Confirm

**% Potency** : 95.48 %

### 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, <sup>1</sup>HNMR, IR and TGA