

CERTIFICATE OF ANALYSIS

(Certificate No. KML001002-01)

Release Date: 11/03/2024

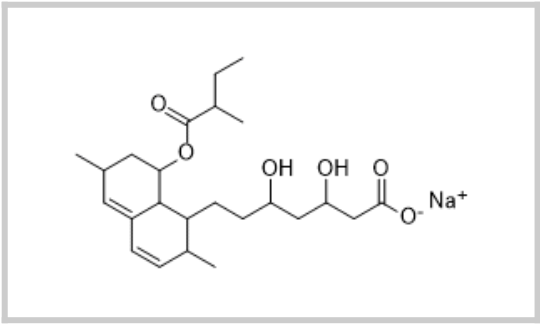
Re-test Date: 10/03/2027

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 | Solubility | : Water |
| Description | : Off white solid | Mass | : Confirm |
| HPLC Purity | : 96.36 % | IR | : Confirm |
| Weight Loss By TGA | : 0.91 % | 1H 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, 1HNMR, IR and TGA