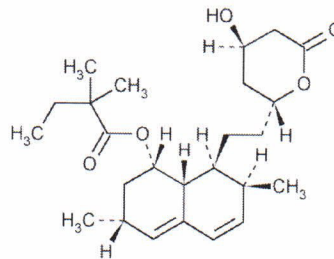


Batch no DK81-2312161
 Mf date Dec 16 2023
 Exp date Dec 15 2026
 Batch size 206.94 kg

Molecular Structure



Molecular Formula C₂₅H₃₈O₅
 Molecular Weight 418.57
 CAS Registry Number 79902-63-9

Jan 15 2024

Tests	Specifications	Results
Appearance	White to off-white powder	Off-white powder
Identification	IR, HPLC	Positive
Specific rotation	+285 ~ +298°	+290.5°
Loss on drying	≤ 0.5%	0.01%
Residue on ignition	≤ 0.1%	0.06%
Chromatographic purity	Simvastatin hydroxylacid ≤ 0.4% Epilovastatin & Lovastatin ≤ 1.0% Methylene simvastatin ≤ 0.4% Acetyl simvastatin ≤ 0.4% Anhydro simvastatin ≤ 0.4% Simvastatin dimer ≤ 0.4% Any other individual impurity ≤ 0.1% Total impurities other than Lovastatin & Epilovastatin ≤ 1.0%	0.04% 0.16% 0.08% 0.07% 0.06% 0.07% < 0.05% 0.35%
Residual solvents	Ethanol ≤ 5000 ppm Dichloromethane ≤ 600 ppm	742 ppm < 76 ppm (LOQ)
Assay (odb)	98.0 ~ 102.0% of C ₂₅ H ₃₈ O ₅	99.8%

Packaging & storage	Preserve in well-closed containers. Store between 15°C and 30°C, or under refrigeration
Conclusion	Material complies with USPNF2023

