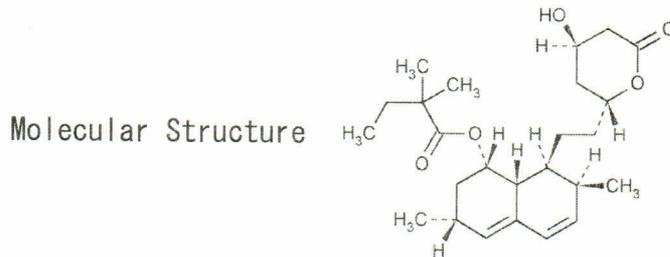


Batch no DK81-22510151
 Mf date Oct 15 2025
 Exp date Oct 14 2028
 Batch size 228.14 kg



Molecular Formula $C_{25}H_{38}O_5$
 Molecular Weight 418.57
 CAS Registry Number 79902-63-9

Jan 16 2026

Tests	Specifications	Results
Appearance	White to off-white powder	Off-white powder
Identification	IR, HPLC	Positive
Specific rotation	+285 ~ +298°	+291.3°
Loss on drying	≤ 0.5%	0.04%
Residue on ignition	≤ 0.1%	0.02%
Chromatographic purity	Simvastatin hydroxylacid ≤ 0.4%	0.05%
	Epilovastatin & Lovastatin ≤ 1.0%	0.15%
	Methylene simvastatin ≤ 0.4%	0.08%
	Acetyl simvastatin ≤ 0.4%	0.06%
	Anhydro simvastatin ≤ 0.4%	0.04%
	Simvastatin dimer ≤ 0.4%	0.11%
	Any other individual impurity ≤ 0.1%	< 0.05%
	Total impurities other than Lovastatin & Epilovastatin ≤ 1.0%	0.38%
Residual solvents	Ethanol ≤ 5000 ppm	738 ppm
	Dichloromethane ≤ 600 ppm	< 76 ppm (LOQ)
Assay (odb)	98.0 ~ 102.0% of $C_{25}H_{38}O_5$	99.4%

Packaging & storage	Preserve in well-closed containers. Store between 15°C and 30°C, or under refrigeration
Conclusion	Material complies with USPNF2025