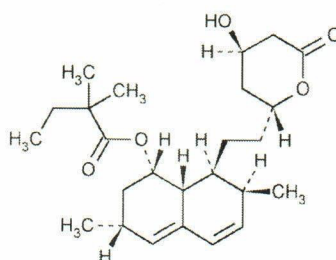


Batch no DK81-22603181
Mf date Mar 18 2026
Exp date Mar 17 2029
Batch size 236.16 kg

Molecular Structure



Molecular Formula $C_{25}H_{38}O_5$

Molecular Weight 418.57

CAS Registry Number 79902-63-9

Jul 20 2026

Tests	Specifications	Results
Appearance	White to off-white powder	Off-white powder
Identification	IR, HPLC	Positive
Specific rotation	+285 ~ +298°	+291.7°
Loss on drying	≤ 0.5%	0.03%
Residue on ignition	≤ 0.1%	0.01%
Chromatographic purity	Simvastatin hydroxylacid	0.04%
	Epilovastatin & Lovastatin	0.11%
	Methylene simvastatin	0.09%
	Acetyl simvastatin	0.09%
	Anhydro simvastatin	0.04%
	Simvastatin dimer	0.11%
	Any other individual impurity	< 0.05%
	Total impurities other than Lovastatin & Epilovastatin	0.42%
		≤ 1.0%
Residual solvents	Ethanol	711 ppm
	Dichloromethane	< 76 ppm (LOQ)
Assay (odb)	98.0 ~ 102.0% of $C_{25}H_{38}O_5$	99.5%

Packaging & storage	Preserve in well-closed containers. Store between 15°C and 30°C, or under refrigeration
Conclusion	Material complies with USP NF 2025

