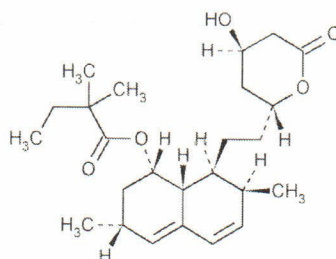


Batch no DK81-22502191
Mf date Feb 19 2025
Exp date Feb 18 2028
Batch size 226.14 kg

Molecular Structure



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

Sep 08 2025

Tests	Specifications	Results
Appearance	White to off-white powder	Off-white powder
Identification	IR, HPLC	Positive
Specific rotation	+285 ~ +298°	+289.6°
Loss on drying	≤ 0.5%	0.05%
Residue on ignition	≤ 0.1%	0.04%
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%
Residual solvents	Ethanol	≤ 5000 ppm
	Dichloromethane	≤ 600 ppm
Assay (odb)	98.0 ~ 102.0% of $C_{25}H_{38}O_5$	99.3%

Packaging & storage	Preserve in well-closed containers. Store between 15°C and 30°C, or under refrigeration
Conclusion	Material complies with USP [®] 2024