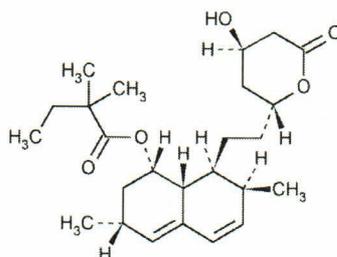


Batch no DK81-22510121
 Mf date Oct 12 2025
 Exp date Oct 11 2028
 Batch size 248.54 kg

Molecular Structure



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

Molecular Weight 418.57

CAS Registry Number 79902-63-9

Dec 19 2025

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
Appearance	White to off-white powder	Off-white powder
Identification	IR, HPLC	Positive
Specific rotation	+285 ~ +298°	+290.9°
Loss on drying	≤ 0.5%	0.02%
Residue on ignition	≤ 0.1%	0.05%
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	727 ppm < 76 ppm (LOQ)
Assay (odb)	98.0 ~ 102.0% of $C_{25}H_{38}O_5$	99.0%

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