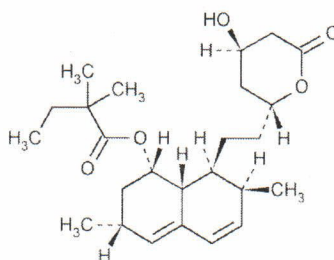


Batch no DK81-22501181  
Mf date Jan 18 2025  
Exp date Jan 17 2028  
Batch size 230.14 kg

Molecular Structure



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

May 28 2025

Tests	Specifications	Results
Appearance	White to off-white powder	Off-white powder
Identification	IR, HPLC	Positive
Specific rotation	+285 ~ +298°	+289.7°
Loss on drying	≤ 0.5%	0.08%
Residue on ignition	≤ 0.1%	0.01%
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 $C_{25}H_{38}O_5$	99.6%

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