



Certificate of analysis

Productname: Simvastatin

Cas number: 79902-63-9

Molecular Formula: C₂₅H₃₈O₅

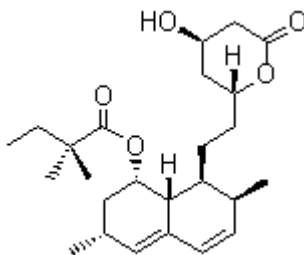
Molecular Weight: 418.57

Date of production: Mar. 22, 2019

Batch No: 20190322

Exp Date: Mar. 21, 2021

Chemical structure:



Items	Specifications	Results
Description	A white or almost white, crystalline powder	Conforms
Identification	IR/UV	Conforms
Specific optical rotation	+285° - +298°	+290.7°
Heavy metals	≤20ppm	<20ppm
Loss on drying	≤0.5%	0.09%
Related Substances		
Simvastatin hydroxyacid	≤0.4%	0.12%
Lovastatin and epilovastatin	≤1.0 %	0.29%
Methylene simvastatin	≤0.4%	0.08%
Acetyl simvastatin	≤0.4%	0.03%
Anhydro simvastatin	≤0.4%	0.07%
Simvastatin dimer	≤0.4%	0.09%
Any other individual impurity	≤0.1%	0.03%
Total impurities (Except lovastatin and epilovastatin)	≤1.0%	0.47%
Assay(on dried basis)	98.0%-102.0%	98.63%

Conclusion: It complies with the USP40 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F