

Lovastatin USP42

Batch no

IF-L0-240605

Mf date Expiry

Jun 05 2024 Jun 04 2027

Molecular Structure H₃c

H₃C H H H H H CH₃

Molecular Formula $C_{24}H_{36}O_5$ Molecular Weight 404.54 CAS Registry Number 75330-75-5

Jun 14 2024

<u>Tests</u>	Specifications	Results
Appearance Solubility	White to off-white crystalline powder Freely soluble in chloroform; soluble in acetone, in acetonitrile, & in methanol; sparingly soluble in alcohol; practically insoluble in hexane; insoluble in water	Conforms Conforms
Identification	IR, UV	Positive
Specific rotation	+324 ~ +338° (5 mg/mL in acetonitrile)	+331. 2°
Loss on drying	≤ 0.3%	0.06%
Residue on ignition	≤ 0.2%	0. 07%
Heavy metals	≤ 0.002%	< 0.002%
Limit of Lovastatin related compound A	≤ 0.5%	0. 18%
Chromatographic purity	Individual impurity ≤ 0.2%	0. 12%
w.	Total impurities ≤ 1.0%	0. 54%
Residual solvents	Butyl acetate ≤ 5000 ppm Acetone ≤ 5000 ppm	20 ppm 179 ppm
Assay (odb)	98.5 $^{\sim}$ 101.0% of $C_{24}H_{36}O_{5}$	98. 8%

Packaging & storage	Preserve in tight containers, under nitrogen in a cold place
Long term storage	Storage temperature: 2 ~ 30°C
Conclusion	Material complies with USP42

