



Certificate of analysis

Product name: Everolimus

Cas number: 159351-69-6

Molecular Formula: $C_{53}H_{83}NO_{14}$

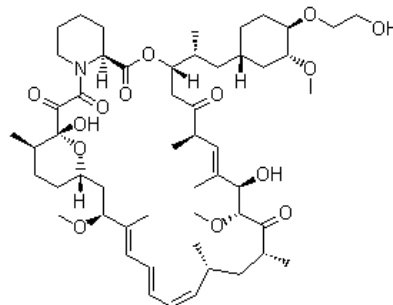
Molecular Weight: 958.22

Date of production: Jan. 07, 2020

Batch NO: 2020107

Exp Date: Jan. 06, 2022

Chemical structure:



Items	Specifications	Results
Appearance	Off- white or white powder	white powder
Identification	IR HPLC UV	Conforms
Specific rotation	-143 ~-153 °	-145.5 °
Heavy metal	≤20ppm	<20ppm
Related substances	EMB ≤0.15%	N.D
	individual unknown impurity ≤0.1%	0.06%
	Total impurities ≤1.0%(Excluding Tautomer, 7-Ring isomer and BHT)	0.20%
Sirolimus	Sirolimus ≤0.15%	N.D
BHT	BHT 1.7%~2.3%	2.0%
Residual Solvents I	Isopropanol ≤1000ppm	N.D
	Dichloromethane ≤600ppm	N.D
	n-Heptane ≤1000ppm	N.D
	Ethylacetate ≤1000ppm	N.D
	Toluene ≤890ppm	4ppm
	1,2-Dimethoxyethane ≤100ppm	N.D
	Methanol ≤3000ppm	678ppm
	Ethanol ≤5000ppm	22ppm
	Triethylamine ≤320ppm	N.D
	Methyl formate ≤100ppm	N.D
Residual solvents II	Ethylene glycol ≤620ppm	N.D
Water	≤2.0%	1.47%
Heavy metal	≤20ppm	Conforms
Residue on ignition	≤0.1%	0.02%
Assay	98.0%~102.0%(on anhydrous and BHT free basis)	98.7%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F