



# Certificate of analysis

Productname: Pimecrolimus

Cas number: 137071-32-0

Molecular Formula: C<sub>43</sub>H<sub>68</sub>ClNO<sub>11</sub>

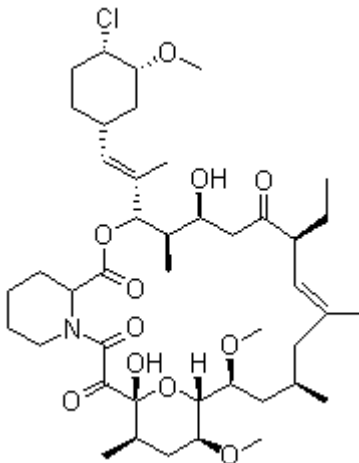
Molecular Weight: 810.45

Date of production: Mar. 11, 2020

Batch NO: 20200311

Exp Date: Mar. 10, 2022

Chemical structure:



Items	Specification	Results
<b>Appearance</b>	White or off-white powder	off-white powder
<b>Specific optical rotation</b>	-105.0° ~-110.0°	-10.7.6°
<b>Identification</b>	HPLC IR	Complies
<b>Residue on ignition</b>	Not more than 0.1%	0.06%
<b>Water</b>	Not more than 2.0%	0.60%
<b>Heavy metals</b>	Not more than 20ppm	Complies
<b>Related substances</b>	Impurity I NMT 0.50%	N.D
	Impurity II NMT 0.50%	0.24%
	Impurity III NMT 0.15%	N.D
	Each of Unspecified impurity(except the tautomer) NMT 0.10%	0.04%
	Total impurities(except the tautomer) NMT 1.0%	0.44%
<b>Residual Solvents</b>	Methanol NMT 3000PPM	N.D
	Acetone NMT 5000PPM	615ppm
	Acetonitrile NMT 410ppm	N.D
	Dichloromethane NMT 600ppm	N.D
	n-Heptane NMT 5000ppm	1271PPM
<b>Microbial Limit</b>	Total Aerobic NMT 100cfu/g	Total Aerobic <10cuf/g
	Total Yeasts and Molds NMT 100cfu/g	Total Yeasts and Molds<10cuf/g
	Staphylococcus aureus should be absent	Absent
	Pseudomonas aeruginosa should be absent	Absent
<b>PSD</b>	D50 NMT 40µm	12.65µm
	D90 NMT 100µm	42.80µm
<b>Assay</b>	98.0% ~ 102.0% (calculated on anhydrous)	99.20%

**Store in a tightly closed container at 2-8° C****Conclusion: It complies with the Enterprise Standard**

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F