



Certificate of analysis

Product name: **Tacrolimus**

Cas number: 104987-11-3

Molecular Formula: $C_{44}H_{69}NO_{12}$

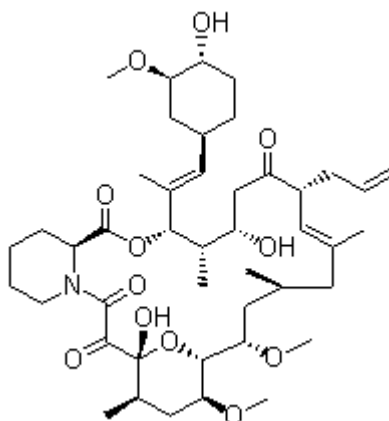
Molecular Weight: 804.02

Date of production: Mar. 10, 2018

Batch no.: 20170810

Exp Date: Mar. 09, 2020

Chemical structure:



Items	Specifications	Results
Appearance	Odorless white powder	Conforms
Identification A	The IR spectrum of Potassium Bromide preparation of the sample exhibits maxilar at the same wavelengths as that of similar preparation of in-house reference standard.	Conforms
Identification B	The retention times of mail peak in the Chromatogram of Assay preparation corresponds to that in the Chromatogram of Standard preparation, as obtained in the Assay	Conforms
Water Content	$\leq 3.0\%$	1.3%
Heavy Metals	$\leq 20\text{ppm}$	Conforms
Total Isomers of Tacrolimus	$\leq 5.0\%$	0.58%
Chromatographic Purity		
Individual Impurity	$\leq 0.5\%$	0.16%
Total Impurities	$\leq 2.0\%$	0.55%
Assay	98.0% to 102%, on the anhydrous basis (including isomers of Tacrolimus)	99.4%
Residual Organic Solvents		
Ethyl Ether	$\leq 5000\text{ppm}$	Not detected
Methyl tert-butyl ether	$\leq 1000\text{ppm}$	Not detected

Conclusion: It complies with Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F

