

SINOWAY INDUSTRIAL CO.,LTD.

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Certificate of Analysis

Product Name:	Tacrolimus	CAS number:	104987-11-3
Batch No.:	20141001	Mfg. Date:	October 10, 2014
Quantity:	10G	Exp. Date:	October 10, 2016

TEST ITEMS	SPECIFICATION	RESULTS
Appearance	A white or almost white powder	Almost white powder
Identification	Positive reaction	Conform
Specific rotation	-82° ~ -90°	-86.0°
Melting range	122 ~ 130°C	123.0 ~ 125.5°C
Water	≤3.0%	2.4 %
Residue on ignition	≤0.2%	0.04%
Heavy metals	≤20 ppm	<20ppm
Related substances	Impurity A (Ascomycin) ≤0.5%	0.10%
	Impurity B(Dihydro tacrolimus)≤0.5%	0.32%
	Any individual unknown impurity ≤0.1 %	0.04%
	Total impurities ≤1.0%	0.52%
Tautomers I+II	≤1.0%	0.22%
Residual solvents	Ethyl ether ≤ 5000 ppm	Conform
	Acetone ≤ 5000 ppm	Conform
	Acetonitrile ≤ 410 ppm	Conform
Assay	98.0% ~ 102.0%	99.3%
CONCLUSION	CONFORM TO ENTERPRISE STANDARD	

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