

NORTH CHINA PHARMACEUTICAL HUASHENG CO., LTD.

CERTIFICATE OF ANALYSIS

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Product name : Tacrolimus

Batch No. : HNTN 1910401E

Manuf. date : 2019.10.30

Cert. No. : P-NT-01

Report date : 2019.12.12

Batch size : 1.661kg

Retest date : 2021.04.29

Tests	Specifications	Results
Characters	White or almost white, crystalline powder	White crystalline powder
Identification	Infrared absorption	Complies
Appearance of solution	Clarity: Should be clear	Clear
	Colour : Not more intensely than reference solution GY ₇	GY ₇
Water	1.5 per cent to 4.0 per cent	3.0%
Sulfated ash	Maximum 0.1 per cent	0.1%
Related substances		
Impurity A	Maximum 0.5 per cent	Not detected
Unspecified impurities	Maximum 0.15 per cent	0.15%
Total	Maximum 1.0 per cent	0.2%
Content(anhydrous substance)	97.0 per cent to 102.0 per cent	100.5%
Residual solvent		
Ethanol	Maximum 0.5%	Not detected
Acetone	Maximum 0.5%	0.001%
Ethyl acetate	Maximum 0.5%	0.004%
Isopropyl ether	Maximum 0.05%	0.0002%

Conclusion : Complies with Ph. Eur.

Reporter: 徐静

Manager of QC division: 杜军

Manager of QA division: 樊芳

