

NORTH CHINA PHARMACEUTICAL HUASHENG CO., LTD.

CERTIFICATE OF ANALYSIS

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Product name : Tacrolimus Monohydrate

Batch No. : HNTN2301501E

Manuf. date : 2023.01.09

Cert. No. : P-NT-01

Report date : 2023.01.20

Batch size : 11.448kg

Retest date : 2025.01.08

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 GY7	GY7
Water	1.5 per cent to 4.0 per cent	2.1%
Sulfated ash	Maximum 0.1 per cent	0.04%
Related substances		
Impurity A	Maximum 0.5 per cent	Not detected
Unspecified impurities	Maximum 0.15 per cent	Not detected
Total	Maximum 1.0 per cent	Not detected
Content(anhydrous substance)	97.0 per cent to 102.0 per cent	100.6%
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%	Not detected

Conclusion : Complies with Ph. Eur. 11.0

Reporter: 徐静

Manager of QC division: 杜军

Qualified Person: 张华胜

