

PHARMACEUTICAL

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19/10/2023

NORTH CHINA PHARMACEUTICAL HUASHENG CO., LTD. CERTIFICATE OF ANALYSIS

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Product name : Tacrolimus Monohydrate

Batch No. : HNTN2306501E

Manuf. date : 2023.06.08

Cert. No. : P-NT-01

Report date : 2023.09.27

Batch size : 10.608kg

Retest date : 2026.06.07

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	2.2%
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	0.10%
Total	Maximum 1.0 per cent	0.2%
Content(anhydrous substance)	97.0 per cent to 102.0 per cent	99.5%
Residual solvent		
Ethanol	Maximum 5000 ppm	Not detected
Acetone	Maximum 5000 ppm	Not detected
Ethyl acetate	Maximum 5000 ppm	63 ppm
Isopropyl ether	Maximum 500 ppm	Not detected

Conclusion : Complies with Ph. Eur

Reporter: 徐静

Manager of QC division: 杜军

Qualified Person: 徐静

