

METAPHARMACEUTICAL

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03/10/2025

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

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Product name : Tacrolimus Monohydrate

Batch No. :	HNTN2508501E	Manuf. date :	2025.08.03
Cert. No. :	P-NT-01	Report date :	2025.08.29
Batch size :	10.163kg	Retest date :	2028.08.02

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	2.4%
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	0.09%
Total	Maximum 1.0 per cent	0.2%
Content(anhydrous substance)	97.0 per cent to 102.0 per cent	100.2%
Residual solvent		
Ethanol	Maximum 5000 ppm	Not detected
Acetone	Maximum 5000 ppm	Not detected
Ethyl acetate	Maximum 5000 ppm	Not detected
Isopropyl ether	Maximum 500 ppm	Not detected

Conclusion : Complies with Ph. Eur.

Reporter: *李洋*

Manager of QC division: *张义*

