

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

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**Product name : Cyclosporine**

Batch No. :	HNCN2407403U	Manuf. date :	2024.07.19
Cert. No. :	P-NC-01	Report date :	2024.08.08
Batch size :	76.815kg	Retest date :	2027.07.18

Tests	Specifications	Results
Characters	White to almost white powder	White powder
Identification	A: Infrared spectroscopy	Complies
	B: The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay	Complies
Loss on drying	≤2.0%	0.6%
Related compounds		
Any individual impurity	≤0.7 %	0.3%
Total impurities	≤1.5 %	0.8%
Assay(on the dried basis)	97.0~101.5%	98.7%
Residual solvent		
Ethanol	≤5000 ppm	79 ppm
Acetone	≤5000 ppm	888 ppm
Ethyl acetate	≤5000 ppm	75ppm
Microbial limits		
TAMC	≤10 <sup>3</sup> cfu/g	<20 cfu/g
TYMC	≤10 <sup>2</sup> cfu/g	<20 cfu/g

**Conclusion : Complies with current USP**

Reporter: 徐静 Manager of QC division: 杜军 Qualified Person: 张强



