

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

Add: No. 8 Yangzi Road, Shijiazhuang Economic & Technological Development Zone, Hebei 052160, China
Tel:+86-311-83090290 Fax:+86-311-83090280 Website: <http://www.ncpchs.com> E-mail: mail@ncpchs.com

Product name : Cyclosporine

Batch No.	: HNCN2102402U	Manuf. date	: 2021.02.27
Cert. No.	: P-NC-01	Report date	: 2021.03.15
Batch size	: 40.105kg	Retest date	: 2024.02.26

Tests	Specifications	Results
Characters	White to almost white powder	White powder
Identification	Complies	Complies
Loss on drying	≤2.0%	0.05%
Related compounds		
Any individual impurity	≤0.7 %	0.3%
Total impurities	≤1.5 %	0.7%
Assay(on the dried basis)	97.0~101.5%	99.0%
Residual solvent		
Ethanol	≤5000 ppm	Not detected
Acetone	≤5000 ppm	Not detected
Ethyl acetate	≤5000 ppm	108 ppm
Microbial limits		
TAMC	≤10 ³ cfu/g	Complies
TYMC	≤10 ² cfu/g	Complies

Conclusion : Complies with USP43

Reporter: 徐静 Manager of QC division: 杜军 Manager of QA division: 魏海平

