

METAPHARMACEUTICAL

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03/10/2025

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 : Ciclosporin

Batch No. :	HNCN2507404E	Manuf. date :	2025.07.26
Cert. No. :	P-NC-01	Report date :	2025.08.18
0Batch :	75.708kg	Retest date :	2029.01.25

Tests	Specifications	Results
Appearance	White or almost white powder	White powder
Identification	IR: Conforms to the reference standard HPLC: The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution(a)	Conforms Conforms
Appearance of solution	Clarity: Should be clear Colour: Not more intensely coloured than reference solution Y5,BY5 or R7	Conforms Y7
Specific optical rotation	-185° ~ -193°	-188°
Loss on drying	≤2.0%	0.5%
Related substances		
Sum of impurities B and E	≤0.5 %	0.2%
Impurity G	≤0.4 %	0.1%
Any other impurity	≤0.3 %	0.2%
Total impurities	≤1.5 %	0.6%
Assay(dried basis)	97.0%~102.0%	99.1%
Bacterial endotoxins	<0.84IU/mg	Conforms
Residual solvent		
Ethanol	≤5000 ppm	Not detected
Acetone	≤5000 ppm	24 ppm
Ethyl acetate	≤5000 ppm	36 ppm
Microbial limits		
TAMC	≤10 ³ cfu/g	<20 cfu/g
TYMC	≤10 ² cfu/g	<20 cfu/g
Escherichia Coli	Negative	Not detected

Conclusion : Complies with EP

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

