

METAPHARMACEUTICAL

N DE LOTE:

0050325

Aljondro
04/03/2025

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

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Product name : Ciclosporin

Batch No. :	HNCN2407401E	Manuf. date :	2024.07.05
Cert. No. :	P-NC-01	Report date :	2024.08.08
Batch size :	78.414kg	Retest date :	2028.01.04

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%	0.8%
Related substances		
Sum of impurities B and E	≤0.5 %	0.3%
Impurity G	≤0.4 %	Not detected
Any other impurity	≤0.3 %	0.1%
Total impurities	≤1.5 %	0.5%
Assay(dried basis)	97.0%~102.0%	99.4%
Bacterial endotoxins	<0.84IU/mg	Conforms
Residual solvent		
Ethanol	≤5000 ppm	Not detected
Acetone	≤5000 ppm	240 ppm
Ethyl acetate	≤5000 ppm	69 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 EP11.0

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

