

Job ACCOUNTS: 161630

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. : HNCN1509403	Manuf. date : 2015.09.27
Cert. No. : P-NC-01	Report date : 2016.01.27
Batch size : 41.340 kg	Retest date : 2017.09.26

Tests	Specifications	Results
Appearance	White or almost white powder	White powder
Identification	IR: Should be complies	Complies
	HPLC: Should be complies	Complies
Appearance of solution	Clarity: Should be clear	Clear
	Colour: No more intensely coloured than reference solution Y5,BY5 or R7	Y7
Specific optical rotation	-193° ~ -185°	-191°
Loss on drying	≤2.0%	0.4%
Heavy metals	≤20ppm	<20ppm
Related compounds		
Any impurity	≤0.7 %	0.3%
Total impurities	≤1.5 %	0.7%
Assay(on the dried basis)	97.0~102.0%	99.1%
Residual solvent		
Ethanol	≤5000 ppm	Not detected
Acetone	≤5000 ppm	Not detected
Ethyl acetate	≤5000 ppm	Not detected

Conclusion : Complies with

Reporter 徐静 Manager of QC division 孙超

