

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

09/04/2024

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: Sirolimus

Batch No. : HNSN2402501

Manuf.date : 2024.02.21

Packing : 0.5kg/tin

Report date : 2024.03.20

Quantity : 1.654 kg

Retest date : 2027.02.20

Cert. No. : P-NS-01

Items	Specifications	Results
Characters:	White crystalline powder	White crystalline powder
Identification	(1)Infrared Absorption	Complies
	(2)The retention time of principle peak in chromatogram obtained from Test solution corresponds to that obtained from Reference solution	Complies
Related substances		
Tautomer,RRT=1.1	≤3.0%	0.7%
Individual impurity	≤1.0%	0.1%
Total impurities	≤3.0%	0.2%
Water	≤1.0 %	0.1%
Residue on ignition	≤0.5 %	0.1%
Heavy metals	≤20 ppm	< 20ppm
Assay(on anhydrous basis)	≥94.0%	99.5%
Residual solvent		
Ethanol	≤2000 ppm	Not detected
Acetone	≤4000 ppm	Not detected
Ethyl ether	≤4000 ppm	Not detected
Isopropyl ether	≤2000 ppm	Not detected
Ethyl acetate	≤4000 ppm	Not detected
Microbial limit		
TAMC	≤10 ³ cfu/g	<20cfu/g
TYMC	≤10 ² cfu/g	<20cfu/g
E.Coli	Absent	Not detected

Conclusion : Complies with <State Food and Drug Administration Standard>
YBH09982005-2015Z

Reporter: 徐静

Manager of QC division:

杜军

Qualified Person: 张强

