

METAPHARMACEUTICAL

N DE LOTE:

0220624

28/06/2024

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

Add: No. 8 Yangzi Road, Shijiazhuang Economic & Technological Development Zone, Hebei 052160, China

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Product name: Sirolimus

Batch No. : HNSN2404501

Manuf.date : 2024.04.08

Packing : 0.5kg/tin

Report date : 2024.04.19

Quantity : 2.241 kg

Expiry date : 2027.04.07

Cert. No. : P-NS-01

Items	Specifications	Results
Characters:	White crystalline powder	White crystalline powder
Identification	(1)Infrared Absorption (2)The retention time of principle peak in chromatogram obtained from Test solution corresponds to that obtained from Reference solution	Complies Complies
Related substances		
Tautomer,RRT=1.1	≤3.0%	1.5%
Individual impurity	≤1.0%	0.2%
Total impurities	≤3.0%	0.3%
Water	≤1.0 %	0.2%
Residue on ignition	≤0.5 %	0.02%
Heavy metals	≤20 ppm	< 20ppm
Assay(on anhydrous basis)	≥94.0%	98.6%
Residual solvent		
Ethanol	≤2000 ppm	Not detected
Acetone	≤4000 ppm	Not detected
Ethyl ether	≤4000 ppm	Not detected
Isopropyl ether	≤2000 ppm	5 ppm
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:

