

bte: 0130719

NORTH CHINA PHARMACEUTICAL HUASHENG CO., LTD.

CERTIFICATE OF ANALYSIS

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Product name: Sirolimus

Batch No. : HNSN1903402

Manuf.date : 2019.03.26

Packing : 0.5kg/tin

Report date : 2019.04.30

Quantity : 3.065 kg

Retest date : 2022.03.25

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%	1.0%
Individual impurity	≤1.0%	0.2%
Total impurities	≤3.0%	0.4%
Water	≤1.0 %	0.1%
Residue on ignition	≤0.5 %	0.2%
Heavy metals	≤20 ppm	< 20ppm
Assay(on anhydrous basis)	≥94.0%	99.7%
Residual solvent		
Acetone	≤4000 ppm	Not detected
Ethyl Ether	≤4000 ppm	Not detected
Ethyl acetate	≤4000 ppm	Not detected
Ethanol	≤2000 ppm	Not detected
Isopropyl ether	≤2000 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

Manager of QA Division: 张金平

