



NORTH CHINA PHARMACEUTICAL GROUP SEMISYNTech CO., LTD RP NO.E5011912106006

CERTIFICATE OF ANALYSIS

Product name: Amoxicillin Trihydrate

Batch number:	5011912106006	Manufacture date:	2019-12-10
Packing:	25kg/drum	Report date:	2019-12-23
Quantity:	744.28kg	Re-test date:	2022-11

ITEMS	SPECIFICATIONS	RESULTS
Characters	A white or almost white crystalline powder	a white crystalline powder
Identification	A: The IR Spectrum is concordant with spectrum of R.S.	conforms
pH	3.5 ~ 5.5	5.0
Specific optical rotation	+290° ~ +315°	+310°
Related substances		
(2R)-2-amino-2-(4-hydroxyphenyl)acetic acid	≤1.0%	0.01%
6- aminopenicillanic acid	≤1.0%	N.D.
Penicilloic acids of amoxicillin	≤1.0%	0.15%
D-(-)-P-hydroxyphenylglycine methyl ester	≤0.1%	0.04%
Penilloic acids of amoxicillin	≤1.0%	0.01%
Amoxicillin diketopiperazines	≤1.0%	0.04%
Amoxicillin dimer	≤1.0%	0.04%
3-(4-hydroxyphenyl)pyrazin-2-ol	≤1.0%	0.01%
Maximum unknown single impurity	≤0.1%	0.07%
Total impurities	≤3.0%	0.4%
Water	11.5% ~ 14.5%	13.1%
Sulphated ash	≤1.0%	0.05%
Assay (on the anhydrous substance)	95.0% ~ 102.0%	100.8%
Methanol	≤1000ppm	92ppm
Bulk density	0.33g/ml ~ 0.4g/ml	0.38g/ml

Conclusion: Complies with Ph.Eur.9.0 and the customer's requirements

Remark: CEP No.R0-CEP 2014-220-Rev 01

Delegated Q.P.

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