NCPC NORTH CHINA PHARMACEUTICAL GROUP SEMISYNTECH CO., LTD RP NO.E5012004096004

CERTIFICATE OF ANALYSIS

Product name: Amoxicillin Trihydrate

Batch number:	5012004096004	Manufacture date:	2020-04-09
Packing:	25kg/drum	Report date:	2020-04-16
Quantity:	741.25kg	Re-test date:	2023-03

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	4.9
Specific optical rotation	+290° ~ +315°	+308°
Related substances		
(2R)-2-amino-2-(4-hydroxyphenyl)acetic acid	≤1.0%	0.005%
6- aminopenicillanic acid	≤1.0%	N.D.
Penicilloic acids of amoxicillin	≤1.0%	0.10%
D-(-)-P-hydroxyphenyglycine methyl ester	≤0.1%	N.D.
Penilloic acids of amoxicillin	≤1.0%	0.02%
Amoxicillin diketopiperazines	≤1.0%	0.02%
Amoxicillin dimer	≤1.0%	0.03%
3-(4-hydroxyphenyl)pyrazin-2-ol	≤1.0%	0.01%
Maximum unknown single impurity	≤0.1%	0.04%
Total impurities	≤3.0%	0.3%
Water	11.5% ~ 14.5%	13.0%
Sulphated ash	≤1.0%	0.08%
Assay *(on the anhydrous substance)*	95.0% ~ 102.0%	100.1%
Methanol	≤1000ppm	68ppm

Conclusion: Complies with Ph.Eur.9.0

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

Delegated Q.P.

Manufacturing Address: No.20 Yangzi Road Shijiazhuang Economic &Technological Development Zone,Hebei,P.R.China
Postcode: 052165 TEL: +86-311-87170197 FAX: +86-311-87170197 E-mail: apincpc@163.com