



武汉福鑫化工有限公司

Wuhan Fortuna Chemical Co.,Ltd

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CERTIFICATE OF ANALYSIS

Product name: Amoxicillin Trihydrate (Micronized)

Batch No.: 5012107291002

Quantity: 200kgs

Date of check: 2021/08/06

Manuf No.: 2021/07/29

Expiry Date: 2025/06

ITEMS	SPECIFICATIONS	RESULTS
Characteristic	White or almost white crystalline powder. Slightly soluble in water, very slightly soluble in ethanol(96%), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Conform
Identification	1) IR 2) TLC 3) A dark yellow color develops	Complies Complies Complies
N,N-Dimethylaniline	≤20ppm	<20ppm
Specific optical rotation	+290° ~+315°	+307°
Related substances	Maximum single impurity ≤ 1.0%	0.1%
Water	11.5%~14.5%	13.1%
Sulphated ash	≤ 1.0%	0.07%
Assay(Calculated as anhydrous substance)	95.0%~102.0%	101.1%
PH	3.5~5.5	4.7
Particle size	100%≤ 20 microns	Complies
Sterility	Sterilized by Gamma-rays	Complies
Conclusion: Complies with requirement of Ph.Eur/BP2021.		

Q.C.: Luo Xiaofeng

Tester: AT02

Re-tester: AT03