



聯邦制藥(珠海)  
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## ZHUHAI UNITED LABORATORIES CO., LTD.

### CERTIFICATE OF ANALYSIS

No: 240728057

Name of product	Amoxicillin Trihydrate Compacted	Batch NO.	30914058003
Packing	25 00kg/drum	Pieces	40 drums +1drum
Batch weight	1025.74kg	Specifications	EP
Mfg Date	12/05/2014	Exp Date	04/2018
Date of testing	21/07/2014	Date of report	28/07/2014
Storage	Store in the airtight container		
CEP No. R1-CEP 2007-191-Rev 01			

TESTS	SPECIFICATIONS	RESULTS	CONCLUSION
[APPEARANCE]	A white or almost white crystalline powder and granule.	A white crystalline powder and granule.	Conforms
[IDENTIFICATION]	Examine by IR absorption spectrophotometry, comparing with the spectrum obtained with amoxicillin trihydrate CRS	Conforms	Conforms
[SOLUBILITY]	It is slightly soluble in water, very slightly soluble in ethanol (96 percent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Conforms	Conforms
[TESTS]			
pH	3.5 ~ 5.5	4.5	Conforms
Specific optical rotation	+ 290 ~ + 315	+299	Conforms
Related substances	Any specified impurity ≤ 1.0% Any unspecified impurity ≤ 0.10% Total impurities ≤ 3.0%	0.30% 0.06%	Conforms
N, N-Dimethylaniline	NMT 20 ppm (Not used in process)	0.75% Conforms	Conforms
Water	11.5% ~ 14.5%	12.8%	Conforms
Sulphated ash	NMT 0.1%	0.080%	Conforms
Assay	95.0% ~ 102.0% $C_{16}H_{19}N_3O_5S$ (calculated on the anhydrous basis).	99.8%	Conforms
Residual solvents			Conforms
a) Acetone	NMT 800 ppm	43 ppm	
b) Dichloromethane	NMT 600 ppm	295 ppm	
c) Triethylamine	NMT 300 ppm	75 ppm	
d) N,N-dimethylacetamide	NMT 1090 ppm	280 ppm	
e) Toluene	NMT 600 ppm	290 ppm	
f) Pivalic acid	NMT 1000 ppm	756 ppm	
Bulk Density	0.45 g/ml ~ 0.65 g/ml	0.55 g/ml	Conforms
Tapped Density	NLT 0.65 g/ml	0.81 g/ml	Conforms
Particle size	NMT 35% of particles: NLT 850 μm NLT 40% of particles: 850 μm ~ 180 μm NMT 30% of particles: NMT 180 μm	7% 74% 19%	Conforms

**CONCLUSION:** The results conform with EP Specifications.

Pharmacopoeia quality: Complies with the current editions of USP, EP & BP  
Manufactured according to ICH Q7 GMP for APIs

REPORTED BY:

徐伟伟

CHECKED BY:

秦菁

APPROVED BY:

