



聯邦制藥 (珠海)
UNITED LABORATORIES (ZHUHAI)

Add: Sanzao Science & Technology Park, National Hi-Tech Zone, Zhuhai, Guangdong - 519040, P. R. China

Tel: +86-756-7766777

Fax: +86-756-7767377

ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

TZDD14083548

No: 240925030

Name of product		Amoxicillin Trihydrate Compacted	Batch NO.	30914098026
Packing		25.00kg/drum	Pieces	40 drums +1drum
Batch weight		1017.22kg	Specifications	EP
Mfg. Date		20/09/2014	Exp.Date	08/2018
Date of testing		20/09/2014	Date of report	25/09/2014
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%	0.25% 0.05% 0.73%	Conforms Conforms Conforms
N, N-Dimethylaniline	NMT 20 ppm (Not used in process)	Conforms	Conforms
Water	11.5% ~ 14.5%	12.9%	Conforms
Sulphated ash	NMT1.0%	0.070%	Conforms
Assay	95.0%~102.0% $C_{16}H_{19}N_3O_5S$ (calculated on the anhydrous basis) .	99.6%	Conforms
Residual solvents			Conforms
a) Acetone	NMT800ppm	66 ppm	
b) Dichloromethane	NMT600ppm	326ppm	
c) Triethylamine	NMT300ppm	59 ppm	
d) N,N-dimethylacetamide	NMT1090ppm	245 ppm	
e) Toluene	NMT600ppm	297 ppm	
f) Pivalic acid	NMT1000ppm	628 ppm	
Bulk Density	0.45 g/ml ~ 0.65g/ml	0.53 g/ml	Conforms
Tapped Density	NLT0.65g/ml	0.75 g/ml	Conforms
Particle size	NMT35% of particles: NLT850 μ m NLT40% of particles: 850 μ m ~ 180 μ m NMT30% of particles: NMT180 μ m	4% 72% 24%	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: 林红

APPROVED BY: 林红

