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ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

TZDD14083548

No: 240925025

Name of product		Amoxicillin Trihydrate Compacted	Batch NO.	30914098021
Packing		25.00kg/drum	Pieces	40 drums +1drum
Batch weight		1024.36kg	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%	Conforms
N, N-Dimethylaniline	NMT 20 ppm (Not used in process)	0.81% Conforms	Conforms
Water	11.5% ~ 14.5%	12.7%	Conforms
Sulphated ash	NMT 1.0%	0.060%	Conforms
Assay	95.0%~102.0% $C_{16}H_{19}N_3O_5S$ (calculated on the anhydrous basis).	99.7%	Conforms
Residual solvents			Conforms
a) Acetone	NMT 800 ppm	68 ppm	
b) Dichloromethane	NMT 600 ppm	356 ppm	
c) Triethylamine	NMT 300 ppm	74 ppm	
d) N,N-dimethylacetamide	NMT 1090 ppm	299 ppm	
e) Toluene	NMT 600 ppm	304 ppm	
f) Pivalic acid	NMT 1000 ppm	781 ppm	
Bulk Density	0.45 g/ml ~ 0.65 g/ml	0.53 g/ml	Conforms
Tapped Density	NLT 0.65 g/ml	0.76 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	6% 73% 21%	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:

