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ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

No: 240728061

Name of product	Amoxicillin Trihydrate Compacted	Batch NO.	30914058007
Packing	25.00kg/drum	Pieces	40 drums +1drum
Batch weight	1023.68kg	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	+300	Conforms
Related substances	Any specified impurity ≤ 1.0% Any unspecified impurity ≤ 0.10% Total Impurities ≤ 3.0%	0.34% 0.06%	Conforms
N, N-Dimethylaniline	NMT 20 ppm (Not used in process)	0.91% Conforms	Conforms
Water	11.5% ~ 14.5%	12.8%	Conforms
Sulphated ash	NMT 1.0%	0.080%	Conforms
Assay	95.0% ~ 102.0% $C_{16}H_{19}N_3O_5S$ (calculated on the anhydrous basis).	99.5%	Conforms
Residual solvents			Conforms
a) Acetone	NMT 800 ppm	46 ppm	
b) Dichloromethane	NMT 600 ppm	315 ppm	
c) Triethylamine	NMT 300 ppm	84 ppm	
d) N,N-dimethylacetamide	NMT 1000 ppm	309 ppm	
e) Toluene	NMT 600 ppm	289 ppm	
f) Pivalic acid	NMT 1000 ppm	787 ppm	
Bulk Density	0.45 g/ml ~ 0.65 g/ml	0.53 g/ml	Conforms
Tapped Density	NLT 0.65 g/ml	0.77 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	5% 76% 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:

CHECKED BY:

APPROVED BY:

徐伟伟

蔡菁

