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ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

No: 240519017

Name of product		Amoxicillin Trihydrate Compacted	Batch NO.	30914057003
Packing		25.00kg/drum	Pieces	40 drums +1drum
Batch weight		1007.68kg	Specifications	EP and Enterprise standard
Mfg Date		12/05/2014	Exp Date	04/2018
Date of testing		12/05/2014	Date of report	19/05/2014
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
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
[IDENTIFICATION]	Examine by IR absorption spectrophotometry comparing with the spectrum obtained with amoxicillin trihydrate CRS	Conforms	Conforms
[TESTS]			
pH	3.5 ~ 5.5	4.5	Conforms
Specific optical rotation	+ 290 ~ + 315	+300	Conforms
Related substances			Conforms
	Any specified impurity ≤ 1.0%	0.28%	
	Any unspecified impurity ≤ 0.10%	0.08%	
	Total impurities ≤ 3.0%	0.81%	
N, N-Dimethylaniline	NMT 20 ppm (Not used in process)	Conforms	Conforms
Water	11.5% ~ 14.5%	12.9%	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)	99.9%	Conforms
Residual solvents			
a) Acetone	NMT 800 ppm	39 ppm	
b) Dichloromethane	NMT 600 ppm	188 ppm	
c) Triethylamine	NMT 300 ppm	58 ppm	
d) N,N-dimethylacetamide	NMT 1090 ppm	218 ppm	
e) Toluene	NMT 600 ppm	254 ppm	
f) Pivalic acid	NMT 1000 ppm	583 ppm	
g) Pyridine	NMT 200 ppm	4 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	4% 77% 19%	Conforms
Microbial Limit	NMT 1000 bacteria per gram. NMT 80 molds and yeasts per gram. E coli should be undetectable in 1 gram	Conforms	Conforms

CONCLUSION: The results conform with EP and Enterprise standard

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

REPORTED BY:

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APPROVED BY:

