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# ZHUHAI UNITED LABORATORIES CO., LTD.

CONTAINER N°: DFSU4057369/40' GP

## CERTIFICATE OF ANALYSIS

D12071110881

NO:220801113

Name of product		Amoxicillin Trihydrate Compacted		Batch NO.		30912078036	
Packing		25.00kg/drum		Pieces		40 drums +1drum	
Batch Weight		1026.38kg		Specifications		EP and Enterprise standard	
Mfg. Date		14/07/2012		Exp.Date		06/2015	
Date of testing		14/07/2012		Date of report		01/08/2012	
Storage		Store in the airtight container					
CEP: No.R0-CEP2007-191-Rev 02							

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 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)			
Appearance of solution	Not more opalescent than reference suspension II (0.5M hydrochloric acid) Not more opalescent than reference suspension II (dilute ammonia R2)	<reference suspension I <reference suspension I	Conforms
pH	3.5 to 5.5	4.5	Conforms
Specific optical rotation	+ 290 to + 315	+301	Conforms
Related substances			Conforms
Any specified impurity	≤ 1.0%	0.36%	
Any unspecified impurity	≤ 0.10%	0.04%	
Total impurities	≤ 3.0%	0.80%	
N, N-Dimethylaniline	NMT 20 ppm (Not used in process)	Conforms	Conforms
Water	11.5% to 14.5%	12.8%	Conforms
Sulphated ash	NMT1.0%	0.080%	Conforms
Assay	95.0%~102.0% C <sub>16</sub> H <sub>19</sub> N <sub>3</sub> O <sub>5</sub> S (Calculated on anhydrous basis)	99.3%	Conforms
Residual solvents			Conforms
a) Acetone	NMT800ppm	57 ppm	
b) Dichloromethane	NMT600ppm	363ppm	
c) Triethylamine	NMT300ppm	60 ppm	
d) N,N-dimethylacetamide	NMT1090ppm	245 ppm	
e) Toluene	NMT600ppm	322 ppm	
f) Pivalic acid	NMT1000ppm	679 ppm	
Bulk Density	0.45 g/ml to 0.65g/ml	0.54 g/ml	Conforms
Tapped Density	NLT0.65g/ml	0.79 g/ml	Conforms
Particle size	NMT15%(≥ 850 μ m) NLT55%(850 μ m~180 μ m) NMT30%(≤ 180 μ m)	5% 77% 18%	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 Q7A GMP for APIs

REPORTED BY:

CHECKED BY:

APPROVED BY:

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