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联邦制药（珠海）
UNITED LABORATORIES (ZHUHAI)

ZHUHAI UNITED LABORATORIES CO., LTD.

CONTAINER N°: DFSU4057369/40' GP

CERTIFICATE OF ANALYSIS

D12071110881 NO:120715012

Name of product	Amoxicillin Trihydrate Compacted	Batch NO.	30912058057
Packing	25.00kg/drum	Pieces	40 drums +1drum
Batch Weight	1016.48kg	Specifications	EP and Enterprise standard
Mfg. Date	21/05/2012	Exp.Date	04/2015
Date of testing	13/07/2012	Date of report	15/07/2012
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)	＜reference suspension Ⅰ	Conforms
	Not more opalescent than reference suspension Ⅱ (dilute ammonia R2)	＜reference suspension Ⅰ	
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%	0.27%	
Any unspecified impurity	≤ 0.10%	0.05%	
Total impurities	≤ 3.0%	0.61%	
N, N-Dimethylaniline	NMT 20 ppm (Not used in process)	Conforms	Conforms
Water	11.5% to 14.5%	12.9%	Conforms
Sulphated ash	NMT1.0%	0.050%	Conforms
Assay	95.0%~102.0% $C_{16}H_{19}N_3O_5S$ (Calculated on anhydrous basis)	99.6%	Conforms
Residual solvents			Conforms
a) Acetone	NMT800ppm	52 ppm	
b) Dichloromethane	NMT600ppm	365ppm	
c) Triethylamine	NMT300ppm	64 ppm	
d) N,N-dimethylacetamide	NMT1090ppm	296 ppm	
e) Toluene	NMT600ppm	325 ppm	
f) Pivalic acid	NMT1000ppm	831 ppm	
Bulk Density	0.45 g/ml to 0.65g/ml	0.54 g/ml	Conforms
Tapped Density	NLT0.65g/ml	0.82 g/ml	Conforms
Particle size	NMT15%(≥850μm)	8%	Conforms
	NLT55%(850μm～180μm)	74%	
	NMT30%(≤180μm)	18%	

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: 方银碧 CHECKED BY: 秦菁 APPROVED BY: 陈子