



聯邦制藥(珠海)
FEDERAL PHARM (ZHUHAI)

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ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

D13080514417

No: 230821064

Name of product	Amoxicillin Trihydrate Compacted	Batch NO.	30913088012
Packing	25.00kg/drum	Pieces	40 drums +1drum
Batch weight	1016.46kg	Specifications	EP and client request.
Mfg. Date	17/08/2013	Exp Date	07/2017
Date of testing	17/08/2013	Date of report	21/08/2013
Storage	Store in the airtight container		
CEP R0-CEP 2007-191-Rev 03			

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
[TESTS]			
pH	3.5 ~ 5.5	4.5	Conforms
Specific optical rotation	+ 290 ~ + 315	+301	Conforms
Related substances	Any specified impurity ≤ 1.0% Any unspecified impurity ≤ 0.10% Total impurities ≤ 3.0%	0.25% 0.04% 0.77%	Conforms Conforms Conforms
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% $C_{16}H_{18}N_2O_5S$ (calculated on the anhydrous basis)	99.4%	Conforms
Residual solvents			Conforms
a) Acetone	NMT 800ppm	57 ppm	
b) Dichloromethane	NMT 600ppm	365ppm	
c) Triethylamine	NMT 300ppm	59 ppm	
d) N,N-dimethylacetamide	NMT 1090ppm	272 ppm	
e) Toluene	NMT 600ppm	301 ppm	
f) Pivalic acid	NMT 1000ppm	668 ppm	
Bulk Density	0.45 g/ml ~ 0.65g/ml	0.52 g/ml	Conforms
Tapped Density	NLT 0.65g/ml	0.77 g/ml	Conforms
Particle size	NMT 35% (≥ 850 μm) NLT 40% (850 μm ~ 180 μm) NMT 30% (≤ 180 μm)	6% 74% 20%	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

CONCLUSION: The results conform with EP and client request.

Pharmacopoeia quality: Complies with the current editions of USP, EP & BP
Manufactured according to ICH Q7A GMP for APIs

REPORTED BY:

蒋瑞

CHECKED BY:

杨建

APPROVED BY:

