



聯邦制藥(珠海)  
UNITED LABORATORIES (ZHUHAI)

Add: Sanzao Science & Technology Park, National Hi-Tech Zone, Zhuhai, Guangdong – 519040, P. R. China

Tel: +86-756-7766777

Fax: +86-756-7767377

## ZHUHAI UNITED LABORATORIES CO., LTD.

### CERTIFICATE OF ANALYSIS

TZDD14020778

No: 140214007

NO: 140214007

Name of product	Amoxicillin Trihydrate Compacted	Batch NO.	30914018002
Packing	25.00kg/drum	Pieces	40 drums +1drum
Batch weight	1021.02kg	Specifications	EP and client request.
Mfg. Date	10/01/2014	Exp.Date	12/2017
Date of testing	12/02/2014	Date of report	14/02/2014
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 $\leq 1.0\%$ Any unspecified impurity $\leq 0.10\%$ Total impurities $\leq 3.0\%$	0.27% 0.05% 0.85%	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%	0.090%	Conforms
Assay	95.0%~102.0% $C_{16}H_{19}N_3O_5S$ (calculated on the anhydrous basis)	100.4%	Conforms
Residual solvents			Conforms
a) Acetone	NMT 800 ppm	40 ppm	
b) Dichloromethane	NMT 600 ppm	339 ppm	
c) Triethylamine	NMT 300 ppm	86 ppm	
d) N,N-dimethylacetamide	NMT 1090 ppm	289 ppm	
e) Toluene	NMT 600 ppm	304 ppm	
f) Pivalic acid	NMT 1000 ppm	734 ppm	
Bulk Density	0.45 g/ml ~ 0.65 g/ml	0.53 g/ml	Conforms
Tapped Density	NLT 0.65 g/ml	0.78 g/ml	Conforms
Particle size	NMT 35% ( $\geq 850 \mu m$ ) NLT 40% ( $850 \mu m \sim 180 \mu m$ ) NMT 30% ( $\leq 180 \mu m$ )	4% 77% 19%	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:

CHECKED BY:

APPROVED BY:

