



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: 140214010

		NO: 140214010	
Name of product	Amoxicillin Trihydrate Compacted	Batch NO.	30914018007
Packing	25.00kg/drum	Pieces	40 drums +1drum
Batch weight	1026.44kg	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	4.4	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% 0.05% 0.73%	Conforms Conforms Conforms
N, N-Dimethylaniline	NMT 20 ppm (Not used in process)	Conforms	Conforms
Water	11.5% ~ 14.5%	12.8%	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)	99.4%	Conforms
Residual solvents			Conforms
a) Acetone	NMT 800 ppm	38 ppm	
b) Dichloromethane	NMT 600 ppm	289 ppm	
c) Triethylamine	NMT 300 ppm	72 ppm	
d) N,N-dimethylacetamide	NMT 1090 ppm	307 ppm	
e) Toluene	NMT 600 ppm	281 ppm	
f) Pivalic acid	NMT 1000 ppm	618 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% (≥ 850 μm) NLT 40% (850 μm ~ 180 μm) NMT 30% (≤ 180 μm)	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:

*[Signature]*

CHECKED BY:

*[Signature]*

APPROVED BY:







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## ZHUHAI UNITED LABORATORIES CO., LTD.

### CERTIFICATE OF ANALYSIS

TZDD14020779

No: 140214004

NO: 140214004

Name of product	Amoxicillin Trihydrate	Batch No.	30814018036
Grade	Normal powder		
Packing	25.00kg/drum	Pieces	40drums+1drum
Batch weight	1014.06kg	Specifications	EP
Mfg. Date	07/01/2014	Exp. Date	12/2017
Date of testing	12/02/2014	Date of report	14/02/2014
Storage	Store in an airtight container.		
CEP: No. R1-CEP 2006-039-Rev 00			

TESTS	SPECIFICATIONS	RESULTS	CONCLUSION
[APPEARANCE]	A white or almost white, crystalline powder.	A white crystalline powder	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]			
pH	3.5 to 5.5	4.5	Conforms
Specific optical rotation	+290 to +315	+304	Conforms
Related substances			Conforms
Any specified impurity	NMT 1.0%	0.25%	Conforms
Any unspecified impurity	NMT 0.10%	0.06%	
Total impurities	NMT 3.0%	0.55%	
N, N-Dimethylaniline	NMT 20 ppm (Not used in process)	Conforms	Conforms
Water	11.5% to 14.5%	13.0%	Conforms
Sulphated ash	NMT 1.0%	0.060%	Conforms
Assay	95.0% to 102.0% $C_{16}H_{19}N_3O_5S$ , calculated on anhydrous basis.	100.3%	Conforms
Residual solvents			
a) Acetone	NMT 800ppm	49ppm	Conforms
b) Dichloromethane	NMT 600ppm	369ppm	Conforms
c) Triethylamine	NMT 300ppm	81ppm	Conforms
d) N,N-dimethylacetamide	NMT 1090ppm	294ppm	Conforms
e) Toluene	NMT 600ppm	403ppm	Conforms
f) Pivalic acid	NMT 1000ppm	670ppm	Conforms
Bulk density	0.15~0.23g/ml	0.21 g/ml	Conforms

CONCLUSION: The product conforms to EP Specifications.

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

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*[Signature]*

CHECKED BY:

*[Signature]*

APPROVED BY:

