



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

TZDD14020779

No: 140214005

Name of product	Amoxicillin Trihydrate	Batch No.	30814018037
Grade	Normal powder		
Packing	25.00kg/drum	Pieces	40drums+1drum
Batch weight	1014.96kg	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%	0.20%	
Any unspecified impurity	NMT 0.10%	0.05%	
Total impurities	NMT 3.0%	0.50%	
N, N-Dimethylaniline	NMT 20 ppm (Not used in process)	Conforms	Conforms
Water	11.5% to 14.5%	13.1%	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.	100.2%	Conforms
Residual solvents			
a) Acetone	NMT 800ppm	49ppm	Conforms
b) Dichloromethane	NMT 600ppm	354ppm	Conforms
c) Triethylamine	NMT 300ppm	75ppm	Conforms
d) N,N-dimethylacetamide	NMT 1090ppm	263ppm	Conforms
e) Toluene	NMT 600ppm	376ppm	Conforms
f) Pivalic acid	NMT 1000ppm	585ppm	Conforms
Bulk density	0.15~0.23g/ml	0.22 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

REPORTED BY:

[Signature]

CHECKED BY:

[Signature]

APPROVED BY:

