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ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

TZDD14083549

No: 240927015

TZDD14083549

Name of product	Amoxicillin Trihydrate	Batch No.	30814098027
Grade	Normal powder		
Packing	25.00kg/drum	Pieces	40drums+1drum
Batch weight	1023.88kg	Specifications	EP
Mfg. Date	24/09/2014	Exp. Date	08/2018
Date of testing	24/09/2014	Date of report	27/09/2014
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%	0.17%	
Any unspecified impurity	NMT 0.10%	0.05%	
Total impurities	NMT 3.0%	0.48%	
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%	0.080%	Conforms
Assay	95.0% to 102.0% $C_{16}H_{19}N_3O_5S$, calculated on anhydrous basis.	100.0%	Conforms
Residual solvents			
a) Acetone	NMT 800ppm	58ppm	Conforms
b) Dichloromethane	NMT 600ppm	354ppm	Conforms
c) Triethylamine	NMT 300ppm	61ppm	Conforms
d) N,N-dimethylacetamide	NMT 1090ppm	261ppm	Conforms
e) Toluene	NMT 600ppm	343ppm	Conforms
f) Pivalic acid	NMT 1000ppm	723ppm	Conforms
Bulk density	0.15~0.23g/ml	0.20 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 Q7 GMP for APIs

REPORTED BY:

徐伟伟

CHECKED BY:

林红

APPROVED BY:

