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ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

CONTAINER N°: INBU5448255/40' GP

D12081611181

No: 220821053

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Name of product	Amoxicillin Trihydrate	Batch No.	30812068036
Packing	25.00kg/drum	Pieces	40drums+1drum
Batch Weight	1009.84kg	Specifications	EP
Mfg. Date	17/06/2012	Exp. Date	05/2015
Date of testing	18/08/2012	Date of report	21/08/2012
Storage	Store in an airtight container.		
CEP: No.R0-CEP2006-039-Rev 02			

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
[TESTS] Appearance of solution	Not more opalescent than reference suspension II (0.5M hydrochloric acid) Not more opalescent than reference suspension II (dilute ammonia R2)	<reference suspension I <reference suspension I	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
pH	3.5 to 5.5	4.5	Conforms
Specific optical rotation	+290 to +315	+303	Conforms
Related substances			
Any specified impurity	NMT 1.0%	0.16%	Conforms
Any unknown impurity	NMT 0.10%	0.03%	
Total impurities	NMT 3.0%	0.38%	
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%	0.070%	Conforms
Assay	95.0% to 102.0% C ₁₆ H ₁₉ N ₃ O ₅ S (Calculated on the anhydrous basis)	100.0%	Conforms
Residual solvents			
a) Acetone	NMT 800ppm	57ppm	Conforms
b) Dichloromethane	NMT 600ppm	348ppm	Conforms
c) Triethylamine	NMT 300ppm	52ppm	Conforms
d) N,N-dimethylacetamide	NMT 1090ppm	271ppm	Conforms
e) Toluene	NMT 600ppm	343ppm	Conforms
f) Pivalic acid	NMT 1000ppm	737ppm	Conforms
Bulk density	0.15g/ml to 0.40g/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 Q7A GMP for APIs

REPORTED BY:

CHECKED BY:

APPROVED BY:

马英

秦菁

