

ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

CONTAINER NO: INBU5448255/40' GP

D12081611181

No: 220821049

Name of product			No: 220821049	
Packing	Amoxicillin Trihydrate	Batch No.	30812078042	
Batch Weight	25.00kg/drum	Pieces	35drums+1drum	
Mfg. Date	877.34kg	Specifications	EP	
Date of testing	14/07/2012	Exp. Date	06/2015	
Storage	18/08/2012	Date of report	21/08/2012	
CEP: No.R0-CEP2006-039-Rev 02		Store in an airtight container.		

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
[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	+304	Conforms
Related substances			
Any specified impurity	NMT 1.0%	0.15%	Conforms
Any unknown impurity	NMT 0.10%	0.04%	
Total impurities	NMT 3.0%	0.41%	
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%	0.070%	Conforms
Assay	95.0% to 102.0% C ₁₆ H ₁₉ N ₃ O ₅ S (Calculated on the anhydrous basis)	100.2%	Conforms
Residual solvents			
a) Acetone	NMT 800ppm	61ppm	Conforms
b) Dichloromethane	NMT 600ppm	378ppm	Conforms
c) Triethylamine	NMT 300ppm	54ppm	Conforms
d) N,N-dimethylacetamide	NMT 1090ppm	249ppm	Conforms
e) Toluene	NMT 600ppm	323ppm	Conforms
f) Pivalic acid	NMT 1000ppm	716ppm	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:

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