



联邦制药(珠海)
UNITE LABORATORIES (ZHUHAI)

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ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

No: 240728058

Name of product	Amoxicillin Trihydrate Compacted	Batch NO	30914058004
Packing	25.00kg/drum	Pieces	40 drums +1drum
Batch weight	1024.40kg	Specifications	EP
Mfg. Date	12/05/2014	Exp. Date	04/2018
Date of testing	21/07/2014	Date of report	28/07/2014
Storage	Store in the airtight container		
CEP:No. R1-CEP 2007-191-Rev 01			

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
[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
[TESTS]			
pH	3.5 ~ 5.5	4.4	Conforms
Specific optical rotation	+ 290 ~ + 315	+300	Conforms
Related substances			Conforms
	Any specified impurity ≤ 1.0%	0.32%	
	Any unspecified impurity ≤ 0.10%	0.07%	
	Total impurities ≤ 3.0%	0.78%	
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%	0.050%	Conforms
Assay	95.0%~102.0% $C_{16}H_{19}N_3O_5S$ (calculated on the anhydrous basis).	99.7%	Conforms
Residual solvents			Conforms
a) Acetone	NMT 800 ppm	43 ppm	
b) Dichloromethane	NMT 600 ppm	294 ppm	
c) Triethylamine	NMT 300 ppm	84 ppm	
d) N,N-dimethylacetamide	NMT 1090 ppm	257 ppm	
e) Toluene	NMT 600 ppm	296 ppm	
f) Pivalic acid	NMT 1000 ppm	734 ppm	
Bulk Density	0.45 g/ml ~ 0.65 g/ml	0.54 g/ml	Conforms
Tapped Density	NLT 0.65 g/ml	0.78 g/ml	Conforms
Particle size	NMT 35% of particles: NLT 850 μm NLT 40% of particles: 850 μm ~ 180 μm NMT 30% of particles: NMT 180 μm	5% 76% 19%	Conforms

CONCLUSION: The results conform with 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:

秦菁

APPROVED BY:





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ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

No: 240518008

Name of product	Amoxicillin Trihydrate Compacted	Batch NO	30914057001
Packing	25.00kg/drum	Pieces	40 drums +1drum
Batch weight	1006.80kg	Specifications	EP and Enterprise standard
Mfg Date	12/05/2014	Exp Date	04/2018
Date of testing	12/05/2014	Date of report	18/05/2014
Storage	Store in the airtight container		
CEP No R1-CEP 2007-191-Rev 01			

TESTS	SPECIFICATIONS	RESULTS	CONCLUSION
[APPEARANCE]	A white or almost white crystalline powder and granule	A white crystalline powder and granule	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
[IDENTIFICATION]	Examine by IR absorption spectrophotometry, comparing with the spectrum obtained with amoxicillin trihydrate CRS	Conforms	Conforms
[TESTS]			
pH	3.5 ~ 5.5	4.5	Conforms
Specific optical rotation	+290 ~ +315	+298	Conforms
Related substances	Any specified impurity ≤ 1.0% Any unspecified impurity ≤ 0.10% Total impurities ≤ 3.0%	0.23% <Reporting limit 0.05% 0.47% threshold	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%	0.080%	Conforms
Assay	95.0% ~ 102.0% $C_{16}H_{19}N_3O_5S$ (calculated on the anhydrous basis)	100.0%	Conforms
Residual solvents			
a) Acetone	NMT 800 ppm	37 ppm	Conforms
b) Dichloromethane	NMT 600 ppm	194 ppm	
c) Triethylamine	NMT 300 ppm	57 ppm	
d) N,N-dimethylacetamide	NMT 1090 ppm	223 ppm	
e) Toluene	NMT 600 ppm	225 ppm	
f) Pivalic acid	NMT 1000 ppm	683 ppm	
g) Pyridine	NMT 200 ppm	2 ppm	
Bulk Density	0.45 g/ml ~ 0.65 g/ml	0.53 g/ml	Conforms
Tapped Density	NLT 0.65 g/ml	0.74 g/ml	Conforms
Particle size	NMT 35% of particles: NLT 850 μm NLT 40% of particles: 850 μm ~ 180 μm NMT 30% of particles: NMT 180 μm	4% 79% 17%	Conforms
Microbial Limit	NMT 1000 bacteria per gram. NMT 80 molds and yeasts per gram E.coli should be undetectable in 1 gram.	Conforms	Conforms

CONCLUSION: The results conform with EP and Enterprise standard

Pharmacopoeia quality: Complies with the current editions of USP, EP & BP
Manufactured according to ICH Q7 GMP for APIs

REPORTED BY:

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CHECKED BY:

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APPROVED BY:

