



聯邦制藥 (珠海)  
FEDERAL PHARM (ZHUHAI)

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## ZHUHAI UNITED LABORATORIES CO., LTD.

### CERTIFICATE OF ANALYSIS

D13080514417

No: 230821063

|                             |                                  |                |                        |
|-----------------------------|----------------------------------|----------------|------------------------|
| Name of product             | Amoxicillin Trihydrate Compacted | Batch NO.      | 30913088011            |
| Packing                     | 25.00kg/drum                     | Pieces         | 40 drums +1drum        |
| Batch weight                | 1017.08kg                        | Specifications | EP and client request. |
| Mfg. Date                   | 17/08/2013                       | Exp Date       | 07/2017                |
| Date of testing             | 17/08/2013                       | Date of report | 21/08/2013             |
| Storage                     | Store in the airtight container  |                |                        |
| CEP: R0-CEP 2007-191-Rev 03 |                                  |                |                        |

| 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                         |
| [TESTS]                   |                                                                                                                                                                                             |                                         |                                  |
| pH                        | 3.5 ~ 5.5                                                                                                                                                                                   | 4.5                                     | Conforms                         |
| Specific optical rotation | + 290 ~ + 315                                                                                                                                                                               | +301                                    | Conforms                         |
| Related substances        | Any specified impurity ≤ 1.0%<br>Any unspecified impurity ≤ 0.10%<br>Total impurities ≤ 3.0%                                                                                                | 0.24%<br>0.04%<br>0.75%                 | Conforms<br>Conforms<br>Conforms |
| N, N-Dimethylaniline      | NMT 20 ppm<br>(Not used in process)                                                                                                                                                         | Conforms                                | Conforms                         |
| Water                     | 11.5% ~ 14.5%                                                                                                                                                                               | 12.9%                                   | Conforms                         |
| Sulphated ash             | NMT 1.0%                                                                                                                                                                                    | 0.060%                                  | Conforms                         |
| Assay                     | 95.0% ~ 102.0% $C_{16}H_{19}N_3O_5S$<br>(calculated on the anhydrous basis)                                                                                                                 | 99.4%                                   | Conforms                         |
| Residual solvents         |                                                                                                                                                                                             |                                         | Conforms                         |
| a) Acetone                | NMT 800 ppm                                                                                                                                                                                 | 62 ppm                                  |                                  |
| b) Dichloromethane        | NMT 600 ppm                                                                                                                                                                                 | 384 ppm                                 |                                  |
| c) Triethylamine          | NMT 300 ppm                                                                                                                                                                                 | 64 ppm                                  |                                  |
| d) N, N-dimethylacetamide | NMT 1090 ppm                                                                                                                                                                                | 290 ppm                                 |                                  |
| e) Toluene                | NMT 600 ppm                                                                                                                                                                                 | 312 ppm                                 |                                  |
| f) Pivalic acid           | NMT 1000 ppm                                                                                                                                                                                | 787 ppm                                 |                                  |
| Bulk Density              | 0.45 g/ml ~ 0.65 g/ml                                                                                                                                                                       | 0.52 g/ml                               | Conforms                         |
| Tapped Density            | NLT 0.65 g/ml                                                                                                                                                                               | 0.77 g/ml                               | Conforms                         |
| Particle size             | NMT 35% (≥ 850 μm)<br>NLT 40% (850 μm ~ 180 μm)<br>NMT 30% (≤ 180 μm)                                                                                                                       | 5%<br>75%<br>20%                        | Conforms<br>Conforms<br>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                         |

**CONCLUSION:** The results conform with EP and client request.

Pharmacopoeia quality: Complies with the current editions of USP, EP & BP  
Manufactured according to ICH Q7A GMP for APIs

REPORTED BY:

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