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聯邦制藥（珠海）
UNITED LABORATORIES (ZHUHAI)

# ZHUHAI UNITED LABORATORIES CO., LTD.

CONTAINER N°: INBU5448255/40' GP

## CERTIFICATE OF ANALYSIS

D12071110881 NO:220801115

| | | | |
|---|---|---|---|
| Name of product | Amoxicillin Trihydrate Compacted | Batch NO. | 30912078039 |
| Packing | 25.00kg/drum | Pieces | 40 drums +1drum |
| Batch Weight | 1025.62kg | Specifications | EP and Enterprise standard |
| Mfg. Date | 15/07/2012 | Exp.Date | 06/2015 |
| Date of testing | 15/07/2012 | Date of report | 01/08/2012 |
| Storage | Store in the airtight container | | |
| CEP: No.R0-CEP2007-191-Rev 02 | | | |

| 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 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) | | | |
| Appearance of solution | Not more opalescent than reference suspension II (0.5M hydrochloric acid) | <reference suspension I | Conforms |
| | Not more opalescent than reference suspension II (dilute ammonia R2) | <reference suspension I | |
| pH | 3.5 to 5.5 | 4.5 | Conforms |
| Specific optical rotation | + 290 to + 315 | +301 | Conforms |
| Related substances | | | Conforms |
| Any specified impurity | ≤1.0% | 0.35% | |
| Any unspecified impurity | ≤ 0.10% | 0.04% | |
| Total impurities | ≤ 3.0% | 0.76% | |
| N, N-Dimethylaniline | NMT 20 ppm (Not used in process) | Conforms | Conforms |
| Water | 11.5% to 14.5% | 12.8% | Conforms |
| Sulphated ash | NMT1.0% | 0.090% | Conforms |
| Assay | 95.0%~102.0% $C_{16}H_{19}N_3O_5S$ (Calculated on anhydrous basis) | 99.5% | Conforms |
| Residual solvents | | | Conforms |
| a) Acetone | NMT800ppm | 59 ppm | |
| b) Dichloromethane | NMT600ppm | 333ppm | |
| c) Triethylamine | NMT300ppm | 53 ppm | |
| d) N,N-dimethylacetamide | NMT1090ppm | 294 ppm | |
| e) Toluene | NMT600ppm | 307 ppm | |
| f) Pivalic acid | NMT1000ppm | 666 ppm | |
| Bulk Density | 0.45 g/ml to 0.65g/ml | 0.53 g/ml | Conforms |
| Tapped Density | NLT0.65g/ml | 0.78 g/ml | Conforms |
| Particle size | NMT15%(≥850 μ m) | 5% | Conforms |
| | NLT55%(850 μ m～180 μ m) | 74% | |
| | NMT30%(≤180 μ m) | 21% | |

**CONCLUSION:** The results conform with EP and Enterprise standard
Pharmacopoeia quality: Complies with the current editions of USP, EP & BP
Manufactured according to ICH Q7A GMP for APIs

**REPORTED BY:** 阿英 CHECKED BY: 秦青 APPROVED BY: 张子

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