



聯邦制藥 (珠海)
UNITED LABORATORIES (ZHUHAI)

Add: Sanzao Science & Technology Park, National Hi-Tech Zone, Zhuhai, Guangdong – 519040, P. R. China

Tel: +86-756-7766777

Fax: +86-756-7767377

ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

CONTAINER N°: DFSU4057369/40° GP

D12071110881

NO:220806003

| | | | |
|-------------------------------------|---------------------------------|----------------|----------------------------|
| Name of product | | Batch NO. | |
| Amoxicillin Trihydrate Compacted | | 30912078038 | |
| Packing | 25.00kg/drum | Pieces | 40 drums +1drum |
| Batch Weight | 1027.16kg | Specifications | EP and Enterprise standard |
| Mfg. Date | 15/07/2012 | Exp.Date | 06/2015 |
| Date of testing | 15/07/2012 | Date of report | 06/08/2012 |
| 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) Not more opalescent than reference suspension II (dilute ammonia R2) | <reference suspension I <reference suspension I | Conforms |
| pH | 3.5 to 5.5 | 4.5 | Conforms |
| Specific optical rotation | + 290 to + 315 | +300 | Conforms |
| Related substances | | | Conforms |
| Any specified impurity | ≤ 1.0% | 0.34% | |
| Any unspecified impurity | ≤ 0.10% | 0.03% | |
| 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% 95.0%~102.0% | 0.090% | Conforms |
| Assay | C ₁₆ H ₁₉ N ₃ O ₅ S (Calculated on anhydrous basis) | 99.9% | Conforms |
| Residual solvents | | | Conforms |
| a) Acetone | NMT800ppm | 58 ppm | |
| b) Dichloromethane | NMT600ppm | 351ppm | |
| c) Triethylamine | NMT300ppm | 58 ppm | |
| d) N,N-dimethylacetamide | NMT1090ppm | 256 ppm | |
| e) Toluene | NMT600ppm | 314 ppm | |
| f) Pivalic acid | NMT1000ppm | 567 ppm | |
| Bulk Density | 0.45 g/ml to 0.65g/ml | 0.54 g/ml | Conforms |
| Tapped Density | NLT0.65g/ml | 0.79 g/ml | Conforms |
| Particle size | NMT15%(≥850 μ m) NLT55%(850 μ m~180 μ m) NMT30%(≤180 μ m) | 4% 78% 18% | 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 Q7A GMP for APIs

REPORTED BY:

CHECKED BY:

APPROVED BY:

马英

秦青

张子
质量专用章
QUALITY STAMP