



聯邦制藥(珠海)
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ZHUHAI UNITED LABORATORIES CO., LTD.

CERTIFICATE OF ANALYSIS

TZDD170821092

No.: 270814008

Ref: 270014000

| | | | |
|---------------------------------|---------------------------------|----------------|---------------|
| Name of product | Amoxicillin Trihydrate | Batch No. | 30817088019 |
| Grade | Normal powder | | |
| Packing | 25.00kg/drum | Pieces | 40drums+1drum |
| Batch weight | 1017.28kg | Specifications | EP |
| Mfg. Date | 08/08/2017 | Exp. Date | 07/2021 |
| Date of testing | 09/08/2017 | Date of report | 14/08/2017 |
| Storage | Store in an airtight container. | | |
| CEP: No. R1-CEP 2006-039-Rev 01 | | | |

| 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 |
| [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] | | | |
| pH | 3.5 to 5.5 | 4.6 | Conforms |
| Specific optical rotation | +290 to +315 (Calculated on the anhydrous basis) | +304 | Conforms |
| Related substances | | | |
| Any specified impurity | NMT 1.0% | 0.21% | Conforms |
| Any unspecified impurity | NMT 0.10% | 0.08% | |
| Total impurities | NMT 3.0% | 0.66% | |
| N, N-Dimethylaniline | NMT 20 ppm (Not used in process) | Conforms | Conforms |
| Water | 11.5% to 14.5% | 13.0% | Conforms |
| Sulphated ash | NMT 1.0% | 0.080% | Conforms |
| Assay | 95.0% to 102.0% $C_{16}H_{19}N_3O_5S$ (calculated on anhydrous basis.) | 100.2% | Conforms |
| Residual solvents | | | |
| a) Acetone | NMT 800ppm | 50ppm | Conforms |
| b) Dichloromethane | NMT 600ppm | 383ppm | |
| c) Triethylamine | NMT 300ppm | 71ppm | |
| d) N,N-dimethylacetamide | NMT 1090ppm | 327ppm | |
| e) Toluene | NMT 600ppm | 328ppm | |
| f) Pivalic acid | NMT 1000ppm | 850ppm | |
| Bulk density | 0.15~0.23g/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 Q7 GMP for APIs

REPORTED BY:

CHECKED BY:

APPROVED BY

马英

龙胜妍

