



F&A PHARMA



联邦制药(内蒙古)  
THE UNITED LABORATORIES (INNER MONGOLIA) CO., LTD.

Address: Bayunnaoer Economy & Technology Park, Inner Mongolia-015000, P.R. China

Tel: +86-478-7862667

Fax: +86-478-7862627

QA审核人/日期:

THE UNITED LABORATORIES (INNER MONGOLIA) CO., LTD.

CERTIFICATE OF ANALYSIS

NO: 05B-22120687

2022-12-17

|                                |                                 |                |                        |
|--------------------------------|---------------------------------|----------------|------------------------|
| Name of Product                | Amoxicillin Trihydrate Powder   | Batch No.      | 221213182              |
| Packing                        | 25 Kg/Drum                      | Pieces         | 41Drums+1              |
| Batch Weight                   | 1038.74Kg                       | Specifications | EP and client requests |
| Mfg. Date                      | 09.12.2022                      | Expiry Date    | 11.2026                |
| Date of Testing                | 09.12.2022                      | Date of Report | 15.12.2022             |
| Storage                        | Store in an airtight container. |                |                        |
| CEP No. R1-CEP 2012-078-Rev 02 |                                 |                |                        |

| TESTS                        | SPECIFICATIONS  | RESULTS                                      | CONCLUSION |
|------------------------------|---|--|------------|
| 1. Appearance                | White or almost white, crystalline powder   | White, crystalline powder                    | Conforms   |
| 2. Identification            | Infrared absorption spectrum obtained with substance to be examined should correspond with that obtained with Amoxicillin trihydrate reference substance. | Conforms                                     | Conforms   |
| 3. pH                        | 3.5~5.5   | 4.9  | Conforms   |
| 4. Specific Optical Rotation | +290°~+315° (Anhydrous substance)   | +304°  | Conforms   |
| 5. Related Substances        | Any specified impurity≤1.0%<br>Any unspecified impurity≤0.20%<br>Total impurities≤3.0%  | Not detected<br>Not detected<br>Not detected | Conforms   |
| 6. Water                     | 11.5%~14.5%   | 12.9%  | Conforms   |
| 7. Sulphated Ash             | ≤0.0%   | 0.04%  | Conforms   |
| 8. N, N-Dimethylaniline      | ≤20ppm  | Not applicable                               |            |
| 9. Acetone                   | ≤800ppm   | Not detected                                 | Conforms   |
| 10. Assay                    | It contains 95.0% ~ 102.0% of Amoxicillin, calculated on the anhydrous basis.   | 100.3%                                       | Conforms   |
| 11. Bulk Density             | 0.15g/mL~0.45g/mL   | 0.34g/ml                                     | Conforms   |
| 12. Particle size            |   |  |            |
| <2μm                         | —   | 2%   |            |
| <50μm                        | —   | 97%  |            |

CONCLUSION: The results conform to EP and client requests.

Note: It complies with CEP No. R1-CEP 2012-078-Rev 02.

N, N-Dimethylaniline is not used in the manufacturing process of this product and is not detectable in final products.

REPORTED BY:

张金

CHECKED BY:

APPROVED BY:

质检部