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THE UNITED LABORATORIES (INNER MONGOLIA) CO., LTD

CERTIFICATE OF ANALYSIS

NO: 05B-23010103

Name of Product	Amoxicillin Trihydrate Powder	Batch No.	221213497
Packing	25 Kg Drum	Pieces	42Drums-1
Batch Weight	1063.54Kg	Specifications	EP 10.8 and client requests
Mfg. Date	23.12.2022	Expiry Date	11.2026
Date of Testing	23.12.2022	Date of Report	02.01.2023
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	4.8	Conforms
4. Specific Optical Rotation	+290 ~ +315 (Anhydrous substance)	+305°	Conforms
5. Related Substances	Any specified impurity ≤ 1.0% Any unspecified impurity ≤ 0.20% Total impurities ≤ 3.0%	Not detected Not detected Not detected	Conforms
6. Water	11.5% ~ 14.5%	13.1%	Conforms
7. Sulphated Ash	≤ 1.0%	0.03%	Conforms
8. N, N-Dimethylaniline	≤ 20ppm	Not applicable	Conforms
9. Acetone	≤ 800ppm	Not detected	Conforms
10. Assay	It contains 95.0% ~ 102.0% of Amoxicillin, calculated on the anhydrous basis.	100.6%	Conforms
11. Bulk Density	0.15g/mL ~ 0.45g/mL	0.34g/mL	Conforms
12. Particle size	< 2μm ≤ 50μm < 100μm	2% 98% 100%	Conforms
13. Microbiological Quantity	1) TAMC NMT 10 ⁵ cfu/g 2) TYMC NMT 10 ⁵ cfu/g 3) E. coli should be undetectable in 1 gram	< 10cfu/g < 10cfu/g Not detected	Conforms

CONCLUSION: The results conform to EP 10.8 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: 齐智慧

CHECKED BY: 李

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