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Q/A 申請人 / 日期:

THE UNITED LABORATORIES (INNER MONGOLIA) CO., LTD

# CERTIFICATE OF ANALYSIS

2020.05.08

NO: 05B-20050268

NO. OSD 20030200

Name of Product	Amoxicillin Trihydrate Powder	Batch No.	200313376
Packing	25 Kg/Drum	Pieces	42Drums+1
Batch Weight	1064.88Kg	Specifications	EP
Mfg. Date	18.03.2020	Expiry Date	02.2024
Date of Testing	19.03.2020	Date of Report	07.05.2020
Storage	Store in an airtight container.		
CEP No. R1-CEP 2012-078-Rev 01			

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	5.0	Conforms
4. Specific Optical Rotation	+290°~+315° (Anhydrous substance)	+306°	Conforms
5. Related Substances	Any specified impurity ≤1.0%	Not detected	Conforms
	Any unspecified impurity ≤0.20%	Not detected	
	Total impurities ≤3.0%	Not detected	
6. Water	11.5%~14.5%	12.8%	Conforms
7. Sulphated Ash	≤1.0%	0.05%	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.	100.4%	Conforms
11. Bulk Density	0.15g/mL~0.45g/mL	0.38g/ml	Conforms

## CONCLUSION: The results conform to EP.

Note: It complies with CEP No. R1-CEP 2012-078-Rev 01.

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

REPORTED BY: 王明

CHECKED BY: 王明

APPROVED BY: 李