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OA审核人/日期:

THE UNITED LABORATORIES (INNER MONGOLIA) CO CLAD

CERTIFICATE OF ANALYSIS

2020 • 03 • 28

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Name of Product	Amoxicillin Trihydrate	Batch No.	200313174	
Packing	25 Kg/Drum	Pieces	42Drums+1	
Batch Weight	1067.08Kg	Specifications	BP	
Mfg. Date	09.03.2020	Expiry Date	02.2024	
Date of Testing	10.03.2020	Date of Report	28.03.2020	

TESTS	SPECIFICATIONS	RESULTS	CONCLUSION
1. Appearance	White or almost white, crystalline	White crystalline	Conforms
en e	powder	powder	
2. Identification	The IR spectrum obtained with the	Conforms	Conforms
	substance to be examined should		
	conform with that obtained with		
	Amoxicillin Trihydrate CRS.		
3. pH	3.5~5.5	4.9	Conforms
4. Specific Optical Rotation	+290~+315	+305	Conforms
5. Related substances	Any impurity≤1.0%	Not detected	Conforms
6. Water	11.5%~14.5%	12.8%	Conforms
7. N,N-Dimethylaniline	≤20ppm	Not applicable	
8. Sulphated Ash	≤1.0%	0.05%	Conforms
9. Methanol	≤3000ppm	144ppm	Conforms
10. Acetone	≤5000ppm	Not detected	Conforms
11. Assay	It contains 95.0%~102.0% of	99.5%	Conforms
	Amoxicillin, calculated on the		
	anhydrous basis.		
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CONCLUSION: The results conform with BP.

Note: N, N-Dimethylaniline is not used in the manufacturing process of this product and is not detectable in final products. It complies with BP.

REPORTED BY:

CHECKED BY

APPROVED BY:

