

# 河南绿园药业有限公司

Henan Lvyuan Pharmaceutical Co.,Ltd.

## 检验报告 Certificate of Analysis

报告编号(Report Code) : 6021220016

品名: Product name:	阿莫西林三水酸重粉 Amoxicillin Trihydrate Compacted	规格: Packing size:	25kg/桶 (drum)
批号: Batch No:	6021122206002	来源: Sample source:	102 车间 Workshop 102
数量: Quantity:	1500.00kg	包装数量: Packing Quantity:	60 桶 (drums)
生产日期: Manufacture date:	2022.06.02	取样日期: Sampling date:	2022.06.03
有效期至: Expiry date:	2025.06.01	报告日期: Report date:	2022.06.10
依据: According to:	BP2017		

检验项目 Item	标准规定 Spec.	检验结果 Result
[性状] [Characteristics]		
外观 Appearance	应为白色或类白色粉末和颗粒 A white or almost white powder and granule	类白色粉末和颗粒 A almost white powder and granule
[鉴别] [Identification]		
红外吸收图谱 Infrared Absorption spectrum	应和对照的图谱一致 Infrared Absorption spectrum accord with the referencee spectrum of Amoxicillin Trihydrate	符合规定 Meets the requirements
[检查] [Tests]		
溶液的澄清度 Appearance of solution	≤II 号浊度标准 The solutions are not more opalescent than reference suspension II	<II
pH	3.5~5.5	4.7
比旋度 Specific optical rotation	+290°~+315°	+301°
有关物质 Related substances	单杂: ≤1.0%; Any impurity: ≤1.0%	单杂: 0.2%; Any impurity:0.2%;
N, N-二甲基苯胺 Dimethylaniline	≤20PPM	本产品中从未使用 Never used in the production
水分 Water	11.5~14.5%	12.6%
硫酸盐灰分 Sulphated ash	≤1.0%	0.07%
含量 [Assay]	以无水物计, 含 C <sub>16</sub> H <sub>19</sub> N <sub>3</sub> O <sub>5</sub> S 95.0% ~102.0% Amoxicillin Trihydrate contains not less than 95.0% and not more than 102.0% of C <sub>16</sub> H <sub>19</sub> N <sub>3</sub> O <sub>5</sub> S, calculated with reference to the anhydrous substance	99.4%

结论: 本品按 BP2017 检验以上项目, 结果符合规定。  
Conclusion: The above product conforms to BP2017

备注 (Remarks) : 1.松密度 (Bulk Density) : 0.7g/ml  
2.紧密度 (Tapped Density) : 0.83g/ml  
3.粒度 (Particle size) 20~80 目(mesh) : 81%

质量管理部经理:  Head of QA:   
审核人:  Checked by:   
报告员:  Reporter: 周珍珍