

河南绿园药业有限公司

Henan Lvyuan Pharmaceutical Co.,Ltd.

检验报告

Certificate of Analysis

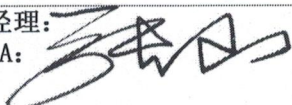
报告编号(Report Code) : 6020220002

品名: Product name:	阿莫西林三水酸 Amoxicillin Trihydrate Powder	规格: Packing size:	25kg/桶 (drum)
批号: Batch No:	6020122205002	来源: Sample source:	102 车间 Workshop 102
数量: Quantity:	300.00kg	包装数量: Packing Quantity:	12 桶 (drums)
生产日期: Manufacture date:	2022.05.04	取样日期: Sampling date:	2022.05.05
有效期至: Expiry date:	2025.05.03	报告日期: Report date:	2022.05.10
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	应为白色或类白色结晶性粉末 A white or almost white, crystalline powder	白色结晶性粉末 A white, crystalline powder
[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	5.0
比旋度 Specific optical rotation	+290°~+315°	+305°
有关物质 Related substances	单杂: ≤1.0%; Any impurity: ≤1.0%	单杂: 0.05%; Any impurity:0.05%;
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%	13.0%
硫酸盐灰分 Sulphated ash	≤1.0%	0.05%
含量 [Assay]	以无水物计, 含 C ₁₆ H ₁₉ N ₃ O ₅ S 95.0% ~102.0% Amoxicillin Trihydrate contains not less than 95.0% and not more than 102.0% of C ₁₆ H ₁₉ N ₃ O ₅ S,calculated with reference to the anhydrous substance	99.6%

结论: 本品按 BP2017 检验以上项目, 结果符合规定。

EP8.0Conclusion: The above product conforms to BP2017

质量管理部经理:
Head of QA: 

审核人:
Checked by: 

报告员:
Reporter: 