

Certificate of analysis

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| 品名 | 氨苄西林钠 Ampicillin sodium | CAS | 69-52-3 |
| 货号 | A6180F | 批次 | 2025A062201 |
| 生产日期 | 2025-06-22 | 复测日期 | 2028-06-22 |

执行标准: 企业标准

| 分析项目 SPECIFICATION PROPERTIES | 技术指标 STANDARD | 实测结果 RESULTS |
|-------------------------------------|---|---|
| 性状 trait | 白色或类白色的粉末或结晶性粉末; 无臭或微臭, 有引湿性 White or off white powder or crystalline powder; Odorless or slightly odorous, with moisture wicking properties | 白色粉末: 无臭, 有引湿性 White powder: odorless, hygroscopic |
| 鉴别1 Identification 1 | 在含量测定项下记录的色谱图中, 供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致。 In the chromatogram recorded under the content determination item, the retention time of the main peak of the test solution should be consistent with that of the main peak of the reference solution. | 符合规定 in compliance with regulations |
| 鉴别2 Identification 2 | 本品的红外光吸收图谱应与对照的图谱(光谱集1283图)一致: 如不一致, 经处理后, 本品的红外光吸收图谱应与氨苄西林的对照图谱(光谱集658图)一致。 | 符合规定 in compliance with regulations |
| 鉴别3 Identification 3 | 本品显钠盐鉴别(1)的反应。 | 符合规定 in compliance with regulations |
| 碱度 alkalinity | pH值8.0~10.0 | 9.1 |

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| 比旋度 specific rotation | +258° ~ +287 | +273° |
| 溶液的澄清度 Clarity of solution | 不得浓于1号浊度标准液 Not thicker than the turbidity standard solution No. 1 | 0.5 |
| 溶液的颜色 Color of solution | 不得深于黄绿色5号标准比色液 Not darker than the yellow green No. 5 standard colorimetric solution | YG0.5 |
| 氨苄西林二聚物 Ampicillin dimer | ≤4.5% | 2.0% |
| 单杂 mono-miscellaneous | ≤2.0% | 0.33% |
| 总杂 general miscellaneous | ≤5.0% | 0.71% |
| 二氯甲烷 Dichloromethane | ≤0.2% | 0.0003% |
| 正丁醇 n-butanol | ≤0.5% | 未检出 Not detected |
| 甲苯 toluene | ≤0.089% | 未检出 Not detected |
| 甲基异丁基酮 methyl isobutyl ketone | ≤0.45% | 未检出 Not detected |
| 异丙醇 isopropanol | ≤0.5% | 未检出 Not detected |
| 乙酸乙酯 ethyl acetate | ≤0.5% | 未检出 Not detected |
| 丙酮 acetone | ≤0.5% | 未检出 Not detected |
| 2-乙基己酸 2-ethylhexanoic acid | ≤0.8% | 未检出 Not detected |
| 重金属 heavy metal | ≤0.0020% | <0.0020% |
| 水分 moisture | ≤2.0% | 0.5% |
| 细菌内毒素 bacterial endotoxin | <0.10EU/mg氨苄西林 | 符合规定 in compliance with regulations |
| 无菌 sterile | 应符合规定 Comply with the regulations | 符合规定 in compliance with regulations |
| 可见异物 visible foreign matter | 应符合规定 Comply with the regulations | 符合规定 in compliance with regulations |

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| 不溶性微粒1 Insoluble particles 1 | 10 μ m及10 μ m以上: ≤6000粒/g | 210粒/g |
| 不溶性微粒2 Insoluble particles 2 | 25um及25 μ m以上: ≤600粒/g | 12粒/g |
| 含量(按无水物计) Content (calculated as anhydrous) | 含C ₁₆ H ₁₉ N ₃ O ₄ S ≥85. 0% | 90. 2% |

注：此产品仅限用于科研，禁止直接用于临床，如有失误，后果自负

QA：杜冰冰

QC：谢辉

