

## CERTIFICATE OF ANALYSIS 检测报告

|                         |                                                                               |                         |                |
|-------------------------|-------------------------------------------------------------------------------|-------------------------|----------------|
| 产品名称<br>Product Name    | 一水肌酸(超细粉)<br>Creatine monohydrate(Micronized Powder)                          |                         |                |
| CAS No.                 | 6020-87-7                                                                     | 批号 Batch Number         | GA35-Y-260601X |
| 参考标准 Reference Standard | Current USP                                                                   | 批量 Batch Size           | 5000kg         |
| 分子式 Molecular Formula   | C <sub>4</sub> H <sub>9</sub> N <sub>3</sub> O <sub>2</sub> ·H <sub>2</sub> O | 生产日期 Manufacturing Date | Jun. 16, 2026  |
| 分子量 Molecular Weight    | 149.15                                                                        | 复测日期 Re-Test Date       | Jun. 15, 2028  |
| 储存条件 Storage Condition: | 保存在密封、耐光的容器中。Preserve in tight, light-resistant containers.                   |                         |                |

| No. | 项目 TEST ITEM                 |                                         | 标准 SPECIFICATION                                                                                                                                                                   | 结果 RESULT            |
|-----|------------------------------|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| 1   | 外观描述 Description             |                                         | 白色粉末 White powder.                                                                                                                                                                 | 白色粉末<br>White powder |
| 2   | 鉴别<br>Identification         | By IR                                   | 样品的测试红外光谱应与以相同方式获得的肌酸参考标准的红外光谱一致。<br>Test infrared spectrum of the sample should concordant with the infrared spectrum of the creatine reference standard obtained in same manner. | 符合 Conform           |
|     |                              | By HPLC                                 | 样品溶液中主峰的保留时间与测定中获得的标准溶液的保留时间相对应。<br>The retention time of the major peak in the sample solution corresponds to that of the standard solution, as obtained in the assay.            | 符合 Conform           |
| 3   | 溶解度 Solubility               |                                         | 微溶于水，不溶于酒精或乙醚<br>Slightly soluble in water , insoluble in alcohol, or ether.                                                                                                       | 符合 Conform           |
| 4   | 干燥失重 Loss on drying          |                                         | 10.5% - 12.5%                                                                                                                                                                      | 10.73%               |
| 5   | 炽灼残渣 Residue on ignition     |                                         | NMT 0.1%                                                                                                                                                                           | 0.02%                |
| 6   | 氯化物和硫酸盐 Chloride and Sulfate |                                         | NMT 0.1%                                                                                                                                                                           | 符合 Conform           |
| 7   | 松密度 Bulk Density             |                                         | 真实值 True value                                                                                                                                                                     | 170g/L               |
| 8   | 紧密度 Tapped Bulk Density      |                                         | 真实值 True value                                                                                                                                                                     | 290g/L               |
| 9   | 相关杂质 Related impurities      | 双氰胺 Dicyandiamide                       | NMT 0.01%                                                                                                                                                                          | 未检出<br>Not Detected  |
|     |                              | 双氢三嗪 Dihydrotriazine                    | NMT 0.0005%                                                                                                                                                                        | 未检出<br>Not Detected  |
|     |                              | 肌酸酐 Creatinine                          | NMT 0.01%                                                                                                                                                                          | 0.004%               |
|     |                              | 任何未指明的杂质<br>Any unspecified impurity    | NMT 0.10%                                                                                                                                                                          | 未检出<br>Not Detected  |
|     |                              | 未指定杂质总数<br>Total unspecified impurities | NMT 1.5%                                                                                                                                                                           | 未检出<br>Not Detected  |
|     |                              | 总杂 Total impurities                     | NMT 2.0%                                                                                                                                                                           | 0.004%               |



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|               |                                        |                                       |                                                                                                    |            |
|---------------|----------------------------------------|---------------------------------------|----------------------------------------------------------------------------------------------------|------------|
| 10            | 微生物检测<br>Microbiological<br>limit test | 菌落总数<br>Total aerobic microbial count | ≤ 10cfu/g                                                                                          | <10cfu/g   |
|               |                                        | 霉菌&酵母<br>Total molds and yeasts       | 不得检出 Absent                                                                                        | 符合 Conform |
|               |                                        | 大肠杆菌<br>Escherichia coli              | 不得检出 Absent                                                                                        | 符合 Conform |
|               |                                        | 沙门氏菌<br>Salmonella species            | 不得检出 Absent                                                                                        | 符合 Conform |
|               |                                        | 金黄色葡萄球菌<br>Staphylococccvs aureus     | 不得检出 Absent                                                                                        | 符合 Conform |
| 11            | 含量 Assay                               |                                       | C4H9N3O2.H2O 按干燥计算为 98.0% ~102.0%。<br>98.0% ~102.0% of C4H9N3O2.H2O calculated on the dried basis. | 100.30%    |
| 结论 Conclusion |                                        |                                       | 所有项目均符合 USP 标准 All items meet the USP.                                                             |            |

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