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## 检验证书

## Certificate of Analysis

|                                |                                                                           |                                                                |
|--------------------------------|---------------------------------------------------------------------------|----------------------------------------------------------------|
| 产品名称: 羟基脲                      |                                                                           |                                                                |
| Product Name: Hydroxycarbamide |                                                                           |                                                                |
| 代号: 210700022014               | 生产批号: VX2026P                                                             | 生产车间: L2100车间                                                  |
| Code:                          | Batch No.:                                                                | Manuf. Workshop: L2100车间                                       |
| 生产日期(年/月/日): 2022/10/28        | 复验日期(年/月/日): 2026/10/27                                                   | 报告日期(年/月/日): 2023/02/24                                        |
| Manuf. Date(Y/M/D):            | Retest Date(Y/M/D):                                                       | Report Date(Y/M/D):                                            |
| 请检数量: 1000kg                   | 包装规格: 25kg/桶                                                              | SHANGHAI ANXIN PHARMACEUTICAL CO., LTD.<br>山东安信制药有限公司<br>质量控制部 |
| Batch Size:                    | Package Size: 25kg/bucket                                                 |                                                                |
| 质量标准号: AX-Q-AM0300B            | 检验标准: Valid Ph.Eur /R1-CEP 2005-051-Rev 04+client's requirements          | SHANGHAI ANXIN PHARMACEUTICAL CO., LTD.<br>质量控制部               |
| Specification Number:          | Specification: Valid Ph.Eur /R1-CEP 2005-051-Rev 04+client's requirements |                                                                |

| 分析                                  | 分项                             | 标准                                                                                        | 结果                       |
|-------------------------------------|--------------------------------|-------------------------------------------------------------------------------------------|--------------------------|
| Analysis                            | Component                      | Specifications                                                                            | Result                   |
| 性状                                  | 性状                             | 白色或类白色结晶性粉末                                                                               | 白色结晶性粉末                  |
| Appearance                          | Appearance                     | White or almost white crystalline powder                                                  | White crystalline powder |
| 鉴别 A                                | 鉴别 A                           | 样品与对照品的红外吸收图谱应一致。                                                                         | 符合规定                     |
| Identification A                    | Identification A               | IR:The spectrum of the sample corresponds to that of RS                                   | Complies                 |
| 鉴别 B                                | 鉴别 B                           | 样品与对照品的主斑点位置大小一致                                                                          | 符合规定                     |
| Identification B                    | Identification B               | TLC:The principal spot of the test solution is similar in position and size to that of RS | Complies                 |
| 脲                                   | 脲                              | ≤0.5%                                                                                     | 符合规定                     |
| Urea(TLC)                           | Urea                           | ≤0.5%                                                                                     | Complies                 |
| 有关物质                                | 杂质A                            | ≤0.1%                                                                                     | <0.02 %                  |
| Related substances(HPLC)            | Impurity A                     | ≤0.1%                                                                                     |                          |
|                                     | 任意其它单个杂质                       | ≤0.05%                                                                                    | <0.02 %                  |
|                                     | Any unspecified impurity       | ≤0.05%                                                                                    |                          |
|                                     | 总杂质                            | ≤0.2%                                                                                     | <0.02 %                  |
|                                     | Total impurities               | ≤0.2%                                                                                     |                          |
| 氯化物                                 | 氯化物                            | ≤50ppm                                                                                    | 符合规定                     |
| Chlorides                           | Chlorides                      | ≤50ppm                                                                                    | Complies                 |
| 水分                                  | 水分                             | ≤0.5%                                                                                     | 0.02 %                   |
| Water                               | Water                          | ≤0.5%                                                                                     |                          |
| 硫酸灰分                                | 硫酸灰分                           | ≤0.1%                                                                                     | 0.01 %                   |
| Sulfated ash                        | Sulfated ash                   | ≤0.1%                                                                                     |                          |
| 含量 (以无水物计)                          | 含量 (以无水物计)                     | 97.5-102.0%                                                                               | 99.7 %                   |
| Assay(on the anhydrous basis)(HPLC) | Assay (on the anhydrous basis) | 97.5-102.0%                                                                               |                          |

QC审核人: 李茂军  
QC Reviewer: 2023/01/04

QA审核人: 李娜  
QA Reviewer: 2023/01/04





| 分析                                | 分项                                                    | 标准                             | 结果               |
|-----------------------------------|-------------------------------------------------------|--------------------------------|------------------|
| Analysis                          | Component                                             | Specifications                 | Result           |
| 溶剂残留<br>Residual solvents(GC<br>) | 甲醇<br>Methanol                                        | ≤3000ppm<br>≤3000ppm           | <34 ppm          |
|                                   | 乙醇<br>Ethanol                                         | ≤5000ppm<br>≤5000ppm           | 161 ppm          |
| 微生物限度<br>Microbial<br>enumeration | 总需氧菌计数<br>Total aerobic microbial<br>count            | ≤1000cfu/g<br>≤1000cfu/g       | <1 cfu/g         |
|                                   | 总霉菌和酵母菌计数<br>Total combined yeasts<br>and molds count | ≤100cfu/g<br>≤100cfu/g         | <1 cfu/g         |
|                                   | 耐胆盐革兰阴性菌<br>Bile-Tolerant Gram-<br>Negative Bacteria  | ≤100cfu/g<br>≤100cfu/g         | <10cfu/g         |
|                                   | 沙门氏菌<br>Salmonella                                    | 不得检出/10g<br>Not detected/10g   | 符合规定<br>Complies |
|                                   | 大肠埃希菌<br>Escherichia coli                             | 不得检出/g<br>Not detected /g      | 符合规定<br>Complies |
| 颗粒度<br>Particle size              | >710μm                                                | ≤15%                           | 5 %              |
|                                   | >710μm                                                | ≤15%                           |                  |
|                                   | <125μm                                                | ≤15%                           | 12 %             |
| 密度<br>Density                     | 松密度<br>The bulk density                               | 0.75~0.95g/ml<br>0.75~0.95g/ml | 0.87 g/mL        |
|                                   | 紧密度                                                   | 0.90~1.10g/ml                  |                  |
|                                   | The tapped density                                    | 0.90~1.10g/ml                  | 1.01 g/mL        |



结论: 本品符合标准Valid Ph.Eur /R1-CEP 2005-051-Rev 04+client' s requirements

Conclusion: This product conforms to the specification Valid Ph.Eur /R1-CEP 2005-051-Rev 04+client' s requirements

储存条件: 密闭, 避光保存

Storage conditions: In a tight container, protect from light

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