

检验报告单

CERTIFICATE OF ANALYSIS

第 1 页, 共 1 页 page 1 of 1

|                          |   |  |                             |
|--------------------------|---|--|-----------------------------|
| 品名<br>Name of product    | 磺胺嘧啶钠<br>Sulfadiazine sodium  | 报告日期<br>Report Date                                | 2021年05月14日<br>May 14, 2021 |
| 批号<br>Lot NO.            | 210502  | 生产日期<br>Manufacture Date                           | 2021年05月05日<br>May 5, 2021  |
| 数量<br>Net weight         | 1050kg  | 有效期至<br>Expiry Date                                | 2024年05月04日<br>May 4, 2024  |
| 检验项目<br>ANALYTICAL ITEMS | 标准规定值<br>SPECIFICATION  | 检验结果<br>ANALYTICAL RESULTS                         |                             |
| 外观<br>Appearance         | 白色或类白色结晶或粉末<br>White or almost white crystalline or powder  | 类白色粉末<br>Almost white powder                       |                             |
| 鉴别 A<br>Identification A | 样品的红外吸收光谱应与磺胺嘧啶CRS红外光谱一致<br>The infrared absorption spectrum concordant with the spectrum of sulfadiazine CRS   | 与对照的图谱一致<br>Concordant with the reference spectrum |                             |
| 鉴别 B<br>Identification B | 钠的反应<br>Test for sodium   | 呈正反应<br>Positive reaction                          |                             |
| 熔点<br>Melting range      | 250°C-254°C   | 250°C-251°C  |                             |
| 硒<br>Selenium            | 不得过 30 ppm<br>Not more than 30 ppm  | 小于 30 ppm<br>Less than 30 ppm                      |                             |
| 残留溶剂<br>Residual solvent | 乙醇不得过5000 ppm<br>Ethanol Not more than 5000 ppm   | 147ppm   |                             |
|                          | 乙酸不得过5000 ppm<br>Acetic acid Not more than 5000 ppm   | ND   |                             |
|                          | DMF不得过880 ppm<br>DMF Not more than 880 ppm  | ND   |                             |
|                          | 甲醇不得过3000 ppm<br>Methanol Not more than 3000 ppm  | ND   |                             |
| 干燥失重<br>Loss on drying   | 不得过 0.5%<br>Not more than 0.5%  | 0.09%  |                             |
| 含量<br>Assay              | 以干品计, 含 C <sub>10</sub> H <sub>9</sub> N <sub>4</sub> O <sub>2</sub> NaS 应不小于 99.0%且不大于 100.5%<br>NLT 99.0% and NMT 100.5% of C <sub>10</sub> H <sub>9</sub> N <sub>4</sub> O <sub>2</sub> NaS, calculated on the dried basis | 99.9%  |                             |
| 检验依据<br>According to     | USPNF 2021  |  |                             |
| 结论<br>Conclusion         | 合格<br>Complies  |  |                             |



检验者: 王美芳  
Analyst: 王美芳 / 2021.09.17

复核者: 严银凤  
Checker: 严银凤 / 2021.09.17

负责人: 缪彩珍  
Supervisor: 缪彩珍 / 2021.09.17