

### 分析证明书

### CERTIFICATE OF ANALYSIS

|   |                             |
|---|-----------------------------|
| Product name 品名: Fusidic Acid 夫西地酸 EP10.5 |                             |
| Batch no.批号:20220801                      | Quantity 数量: 50kgs          |
| Manuf. date 生产日期: 2022/08/28              | Expiry date 有效期: 2024/08/28 |

| 项目 TEST                                 | 标准 SPECIFICATIONS  | 结果 RESULT |
|---|--|-----------|
| Characteristic                          | white or almost white, crystalline powder                                      | Conform   |
| Solubility                              | Practically insoluble in water and easily soluble in ethanol (96percent)       | Conform   |
| Identification                          | IR absorption spectrum of sample is identical with that of reference substance | Conform   |
|   | The residue does not give reaction(a) of sodium                                | Conform   |
| Water                                   | 1.4%~2.0%  | 1.5%      |
| Sulphated Ash                           | ≤0.2%  | 0.12%     |
| Related substance                       | Impurity M≤1.0%  | 0.12%     |
|   | Impurity G≤0.7% <sup>%%</sup>  | ND        |
|   | Impurity L≤0.5%  | ND        |
|   | Impurity B≤0.4%  | ND        |
|   | Impurity A≤0.3%  | ND        |
|   | Impurity H≤0.10%   | ND        |
|   | Impurity C≤0.2%  | 0.1%      |
|   | Impurity D≤0.2%  | ND        |
|   | Impurity F≤0.2%  | ND        |
|   | Impurity I≤0.2%  | 0.08%     |
|   | Impurity K≤0.2%  | ND        |
|   | Impurity N≤0.2%  | ND        |
|   | Any other impurity≤0.1%  | 0.07%     |
| Total impurity≤2.0%                     | 0.2%   |           |
| Assay(Anhydrous)                        | 97.5%~101%   | 99.98%    |
| Conclusion: The product complies EP10.5 |  |           |

复核人:  
Checker:

化验人:  
Analyst:

