

Address: No. 41, Floor 6, Building 4, No. 52 Huangyang Street, High & New Technology Industrial Development Zone, Zhengzhou, 450000, Henan, China.

Phone: 86-371-63507389

Fax: 86-371-63507390

Website: <http://www.sigmachem.cn>

Email: [zzyuanli@zzyuanli.cn](mailto:zzyuanli@zzyuanli.cn)

## Certificate of Analysis

### 质量检验单

|                                                  |                                                                                                                           |                                |                    |
|--------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------|
| Product Name (产品名称): Rifamycin Sodium<br>(利福霉素钠) |                                                                                                                           | Batch No. (批号): 201805008      |                    |
| CAS No.: 14897-39-3                              |                                                                                                                           | Quantity (批量): 400kg           |                    |
| Manufacturing Date (生产日期): 05/08/2018            |                                                                                                                           | Expired Date (失效日期):04/30/2020 |                    |
| Sampling Date (送检日期): 05/08/2018                 |                                                                                                                           | Report Date (报告日期): 05/15/2018 |                    |
| Test Items(检测项目)                                 | Requirements (标准)                                                                                                         |                                | Results (结论)       |
| Appearance (外观)                                  | A fine or slightly granular, red powder, soluble in water, freely soluble in anhydrous ethanol .<br>(红色结晶性粉末，溶于水，易溶于无水乙醇) |                                | Complies (符合规定)    |
| Identification (鉴别)                              |                                                                                                                           |                                |                    |
| A)Infrared Spectrum 红外鉴别                         | Meets the requirments (应符合规定)                                                                                             |                                | Complies (符合规定)    |
| B)Sodium 钠盐反应                                    | Meets the requirments (应符合规定)                                                                                             |                                | Complies (符合规定)    |
| pH                                               | 6.5 ~ 8.0                                                                                                                 |                                | 7.2                |
| Absorbance (吸收系数)                                | 190 ~ 210                                                                                                                 |                                | 192                |
| Related substances<br>(有关物质)                     | Impurity A ≤ 0.5%<br>Impurity B ≤ 2.0%<br>Other Impurities ≤ 2.0%                                                         |                                | 0%<br>0.2%<br>0.6% |
| Heavy Metals (重金属)                               | ≤ 10PPM                                                                                                                   |                                | < 10PPM            |
| Water (水分)                                       | 12.0 ~ 17.0%                                                                                                              |                                | 14.0%              |
| Bacterial Endotoxins<br>(细菌内毒素)                  | ≤ 0.50 I.U./mg                                                                                                            |                                | < 0.50 I.U./mg     |
| Abnormal Toxicity (异常毒性)                         | Meets the requirments (应符合规定)                                                                                             |                                | Complies           |
| Residual Solvents: Butyl acetate<br>(乙酸丁酯残留)     | ≤ 0.50%                                                                                                                   |                                | 0.1%               |
| Assay (含量)                                       | Min. 900 I.U. /mg                                                                                                         |                                | 925 I.U. /mg       |
| Conclusion (结论)                                  | The product conforms with EP8. (本品符合 EP8 标准。)                                                                             |                                |                    |
| Checker (检验人):<br>Junlin Ma                      | Rechecker (复检人):<br>Jing Zhao                                                                                             | Supervisor (主管):<br>Xuezhe Han |                    |