

## 济南久隆医药科技有限公司

## JINAN JIULONG PHARMACEUTICAL TECHNOLOGY CO., LTD.

## **CERTIFICATE OF ANALYSIS**

质检报告

| 产品名称                     | 阿福拉纳<br>Afoxolaner   |                       |                             |
|--------------------------|--|-----------------------|-----------------------------|
| Product Name<br>批号       |  |                       |                             |
| Batch No.                | 20230801   | 生产日期<br>MFG. Date     | 2023.08.04                  |
| 检验日期<br>Date of Analysis | 2023.08.09   | 有效期<br>EXP. Date      | 2026.08.03                  |
| 报告日期<br>Date of Report   | 2023.08.10   | 检验标准<br>Test Standard | 企业标准<br>Enterprise Standard |
| 项目<br>Item               | 标准<br>Specifications   |                       | 分析结果<br>Test Results        |
| 外观<br>Appearance         | 白色或类白色粉末   |                       | 白色粉末                        |
|                          | White or off white powder  |                       | White powder                |
| 溶解度<br>Solubility        | 本品在二甲基亚砜中略溶  |                       | 符合要求                        |
|                          | Slightly soluble in dimethyl sulfoxide   |                       | Conforms                    |
| 鉴别<br>Identification     | 在含量检测项下,样品的出峰时间和标准品出峰时间一致<br>The retention time of the major peak of the assay preparation             |                       |                             |
|                          | corresponds to that of the standard preparation, as obtained in  |                       | 刊 日 安 孙                     |
|                          | the assay.   |                       |                             |
|                          | 单个杂质<  |                       |                             |
| 有关物质                     | Individual Impurities≤0.3%   |                       | 符合要求                        |
| Related Substances       | 总杂≤1.0%  |                       | Conforms                    |
|                          | Total Impurities≤1.0%  |                       |                             |
|                          | 甲苯<0.089%  |                       |                             |
|                          | Methylbenzene≤0.089%   |                       |                             |
| 残留溶剂                     | 乙酸乙酯≤0.5%  |                       | 符合要求                        |
| Residual Solvent         | Ethyl acetate≤0.5%   |                       | Conforms                    |
|                          | 正庚烷≤0.5%   |                       |                             |
|                          | n-Heptane≤0.5%   |                       |                             |
| 水分<br>Water              | ≤1.0%  |                       | 0.5%                        |
| 炽灼残渣                     | 不得过 0.1%   |                       | 符合要求                        |
| Residue on Ignition      | Not more than 0.1%   |                       | Conforms                    |
| 重金属                      | 不得过百万分之十   |                       | 符合要求                        |
| Heavy Metals             | Not more than 10ppm  |                       | Conforms                    |
| 含量<br>Assay              | 按无水物计算含 C <sub>26</sub> H <sub>17</sub> ClF <sub>9</sub> N <sub>3</sub> O <sub>3</sub> 应为 98.0%~102.0% |                       |                             |
|                          | Calculated as anhydrous, the content of $C_{26}H_{17}ClF_9N_3O_3$                                      |                       | 99.0%                       |
|                          | should be 98.0%~102.0%   |                       |                             |
| 贮藏                       | 在低于30C的温度下,密封保存,防潮、  |                       | 朝、避光                        |
| Storage                  | Store in well closed container below $30^\circ\!\!\!\mathrm{C}$ , keep away from me                    |                       | om moisture and sunlight.   |
| 结论                       | 符合企业标准。  |                       |                             |
| Conclusion               | Conforms to Enterprise Standard.   |                       |                             |

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