

# 山东久隆恒信药业有限公司

SHANDONG JIULONG HISINCE PHARMACEUTICAL CO.,LTD

## 分析报告单

## Certificate of Analysis

|                             |  |                      |                          |
|-----------------------------|--|----------------------|--------------------------|
| 品名<br>Product Name          | 氟尼辛葡甲胺<br>Flunixin Meglumine   | 批号<br>Batch No.      | 202406028                |
| 数量<br>Quantity              | 600KG  | 生产日期<br>MFG Date     | JUN.18, 2024             |
| 检验日期<br>Date of analysis    | JUN.29, 2024   | 有效期<br>EXP Date      | JUN.17, 2026             |
| 分析项目<br>Analysis Item       | 标准<br>Standard   | 分析结果<br>Test results | 项目结论<br>Items Conclusion |
| 鉴别<br>Identification        | 红外吸收: 197M<br>Infrared absorption:197M   | 符合规定<br>Conforms     | 符合规定<br>Conforms         |
|                             | 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 sample solution corresponds to that of the standard solution, as obtained in the assay | 符合规定<br>Conforms     | 符合规定<br>Conforms         |
| PH 值                        | 7.0~9.0  | 8.3                  | 符合规定<br>Conforms         |
| 干燥失重<br>Loss on drying      | ≤0.5%  | 0.1%                 | 符合规定<br>Conforms         |
| 比旋度<br>Specific rotation    | -9.0°~-12.0°   | -11.1°               | 符合规定<br>Conforms         |
| 炽灼残渣<br>Residue on ignition | ≤0.2%  | 0.08%                | 符合规定<br>Conforms         |
| 有关物质<br>Related Substances  | 杂质 A ≤0.2%<br>Impurity A ≤0.2%   | ND                   | 符合规定<br>Conforms         |
|                             | 杂质 B ≤0.2%<br>Impurity B: ≤0.2%  | 0.02%                | 符合规定<br>Conforms         |
|                             | 杂质 C ≤0.2%<br>Impurity C: ≤0.2%  | 0.01%                | 符合规定<br>Conforms         |
|                             | 氟尼辛乙酯 ≤0.2%<br>Impurity D: ≤0.2%   | ND                   | 符合规定<br>Conforms         |
|                             | 其他单一杂质 ≤0.2%<br>Any other individual impurity ≤0.2%  | 0.02%                | 符合规定<br>Conforms         |
|                             | 总杂 ≤0.5%<br>Total Impurities ≤0.5%   | 0.05%                | 符合规定<br>Conforms         |
| 含量<br>Assay                 | 98.0%~102.0%   | 98.8%                | 符合规定<br>Conforms         |
| 结论<br>Conclusion            | 本品符合 USP43 标准。<br>Complies with USP43.   |                      |                          |

品质保证部批准:  
Chief of Q.A.Dep.:

受控

复核人:  
Reinspector:

刘梅

化验员:  
Analyst:

王瑞萍

