



山东国邦药业有限公司

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COA template No. : COA-E402055-04-1

质量检验报告书

CERTIFICATE OF ANALYSIS

样品编号(Serial No.)IA7112510107

|                          |                               |                        |                       |
|--------------------------|-------------------------------|------------------------|-----------------------|
| 检品名称<br>Product          | 盐酸多西环素<br>Doxycycline Hyclate | 批号<br>Batch No.        | 711-2510090           |
| 包装<br>Packaging Size     | 25kg/桶 (Drum)                 | 数量<br>Quantity         | 1190.12kg             |
| 生产日期<br>MFG Date         | 24/10/2025<br>(d/m/y)         | 报告日期<br>Reporting Date | 14/11/2025<br>(d/m/y) |
| 执行标准<br>According to     | 《美国药典》43<br>USP43             | 复测日期<br>Re-test Date   | 23/10/2027<br>(d/m/y) |
| 发货数量<br>Shipped quantity |                               |                        |                       |

| 检验项目<br>Tests              | 标准<br>Acceptance Criteria   | 结果<br>Results    | 结论<br>Conclusion |
|----------------------------|---|------------------|------------------|
| 性状<br>Characters           | 黄色至深黄色, 结晶或结晶性粉末<br>Yellow to dark yellow, crystals or crystalline powder.  | 符合规定<br>Conforms | 符合规定<br>Conforms |
| 鉴别<br>Identification       | IR: 供试品红外吸收图谱应与对照图谱一致。<br>The infrared absorption spectrum should be consistent with the reference map.   | 符合规定<br>Conforms | 符合规定<br>Conforms |
| 酸度<br>pH                   | 2.0~3.0   | 2.5              | 符合规定<br>Conforms |
| 水分<br>Water                | 1.4%~2.8%   | 1.9%             | 符合规定<br>Conforms |
| 有关物质<br>Related substances | 4-差向多西环素 4-epidoxycycline≤0.5%.   | 0.14%            | 符合规定<br>Conforms |
|                            | 6-差向多西环素 6-epidoxycycline≤2.0%.   | 0.74%            |                  |
|                            | 美他环素 Methacycline≤2.0%.   | 0.03%            |                  |
|                            | 其他单个杂质 Other impurity≤0.5%.   | 0.45%            |                  |
| 含量<br>Assay                | 按无水与无乙醇物计算, 含 C <sub>22</sub> H <sub>24</sub> N <sub>2</sub> O <sub>8</sub> 在<br>800µg/mg~920µg/mg (On the anhydrous and<br>ethanol-free substance) | 907µg/mg         | 符合规定<br>Conforms |

结论: 本品按《美国药典》43 版标准检验, 结果符合规定。

Conclusion: Conforms to USP43 for Doxycycline hyclate.

备注 (Note):

报告人: 11.14 审核人: 2025.11.14 批准人: 2025.11.14  
Reported by: Reviewed by: Approved by: