



常州亚邦齐晖医药化工有限公司  
CHANGZHOU YABANG-QH PHARMACHEM CO., LTD

FAGRON IBÉRICA, S.A.U  
Corresponde al lote de Fagron:

L14010183

检验报告书  
Certificate of Analysis

  
Director Técnico

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|                                       |                                                           |                                    |            |
|---------------------------------------|-----------------------------------------------------------|------------------------------------|------------|
| 产品名称<br>Product                       | 盐酸左旋咪唑<br>Levamisole Hydrochloride                        | 批号<br>Batch #                      | 61213044   |
| 生产日期<br>Manufacture Date              | 2013.05.27                                                | 有效日期<br>Expiry Date                | 2017.05.26 |
| 数量<br>Quantity                        | 200KG                                                     |                                    |            |
| 储存条件<br>Storage Conditions            | 密闭、避光保存<br>Kept in closed container, protected from light |                                    |            |
| 检验依据<br>Specification                 | EUROPEAN PHARMACOPOEIA 7.0                                |                                    |            |
| 检验项目Test Items                        | 检验标准Specifications                                        | 检验结果Results                        |            |
| 【性状 Description】                      |                                                           |                                    |            |
| 外观<br>Appearance                      | 白色或类白色结晶粉末<br>White or almost white crystalline powder.   | 白色结晶粉末<br>White crystalline powder |            |
| 【鉴别 Identification】                   |                                                           |                                    |            |
| 红外<br>IR                              | 应与对照图谱一致<br>Complies with reference spectrum.             | 符合规定<br>Complies                   |            |
| 氯化物<br>Chloride                       | 应呈正反应<br>Positive.                                        | 符合规定<br>Complies                   |            |
| 【有关物质(HPLC) Related Substances(HPLC)】 |                                                           |                                    |            |
| 总杂质<br>Total Impurities               | ≤0.30%                                                    | 0.10%                              |            |
| 单个已知杂质<br>Individual Specified        |                                                           |                                    |            |
| 杂质A<br>Impurity A                     | ≤0.20%                                                    | <0.05%                             |            |
| 杂质B<br>Impurity B                     | ≤0.20%                                                    | 0.10%                              |            |
| 杂质C<br>Impurity C                     | ≤0.20%                                                    | <0.05%                             |            |
| 杂质D<br>Impurity D                     | ≤0.20%                                                    | <0.05%                             |            |
| 杂质E<br>Impurity E                     | ≤0.20%                                                    | <0.05%                             |            |

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| 检验依据<br>Specification                                                            | EUROPEAN PHARMACOPOEIA 7.0                                                       |                     |            |
| 检验项目 Test Items                                                                  | 检验标准 Specifications                                                              | 检验结果 Results        |            |
| 其它未知杂质<br>Individual unspecified impurities                                      | $\leq 0.10\%$                                                                    | $< 0.05\%$          |            |
| 【溶液颜色和澄清度<br>Color and clarity of the solution】                                  | 清澈, 颜色应低于对照溶液Y7<br>Clear, not more intensely colored than reference solution Y7. | 符合规定<br>Complies    |            |
| 【干燥失重 Loss on Drying】                                                            | $\leq 0.5\%$                                                                     | 0.3%                |            |
| 【硫酸灰份 Sulphated Ash】                                                             | $\leq 0.1\%$                                                                     | 0.1%                |            |
| 【重金属 Heavy metals】                                                               | $\leq 20\text{ppm}$                                                              | $< 20\text{ppm}$    |            |
| 【旋光度 (以干品计) Specific optical rotation】                                           | $-121.0^{\circ} \sim -128.0^{\circ}$                                             | $-125.8^{\circ}$    |            |
| 【pH 值 pH value】                                                                  | 3.0 - 4.5                                                                        | 4.5                 |            |
| 【含量 (以干品计) Assay (Dried substance)】                                              | 98.5% - 101.0%                                                                   | 99.5%               |            |
| 结论: 检验结果符合EP7.0标准<br>Conclusion: The items tested meet the requirements of EP7.0 |                                                                                  |                     |            |
|                                                                                  |                                                                                  |                     |            |
| 审核人/日期:<br>Reviewed by QA Manager/Date                                           | 批准人/日期:<br>Approved By Quality Director/Date                                     |                     |            |

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