

Kalchem International

Chemicals & Compounding Supplies

质量检验报告/Certificate of Analysis

报告号/Report No:

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|----------------------|--|--------------------|----------------------------|------------------|----------------|----------------------------|------------|
| 产品名称 Product Name | 盐酸苯海拉明 C ₁₇ H ₂₁ NO·HCl Diphenhydramine Hydrochloride | | | | 数量 Quantity | 10kg | |
| 包装 Packaging | 25kg/桶 | 批号 Batch Number | 140115 | 有效期 Exp. Date | 09/01/2018 | 生产日期 Manufacturing Date | 10/01/2014 |
| 检验项目 Test Items | 全检 Full Test | | 报告日期 Report Date | | 15/01/2014 | | |
| 样品来源 Sample From | 仓库 Warehouse | 抽样部门 Sampled By | 由 QC 负责抽样 Sampled by QC | | | | |

检验依据: 美国药典 32 版

Basis for Analysis: Based on USP 32

| 检验项目 Test Items | 接受标准/Specification | 检验结果/Test Result |
|--|--|-------------------------------------|
| 外观 Appearance | 白色结晶性粉末 White Crystalline powder | 白色结晶性粉末 White Crystalline powder |
| 熔点 Melting point | 167.0~172.0℃ | 167.8~169.2℃ |
| 鉴别 Identification | A、C 应呈正反应 Positive Reaction B 应符合规定 Should Complies | 符合 Complies |
| 有机挥发性杂质 Organic volatile impurities | 应符合规定 Should Complies | 符合 Complies |
| 干燥失重 Loss on Drying | ≤0.5% | 0.19% |
| 炽灼残渣 Residue on Ignition | ≤0.1% | 0.06% |
| 含量 Assay | 98.0%~102.0% | 99.48% |

结论: 本品按美国药典 32 版检验, 结论符合规定

Conclusion: The test results above USP 32

签署 (Signature)

化验室负责人

检验员

QA Supervisor

QC Supervisor

Analyst

质量检验专用章

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