



福建福瑞明德药业有限公司
FUJIAN FREEMIND PHARM CO., LTD

质量分析报告

Certificate of Analysis

文件编号: SOR-QS-C04-01

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|-------------------------------|---|--------------------|
| 产品名称 Product: | (R)-2,6-二氨基-4,5,6,7-四氢苯并噻唑 | |
| CAS No.: | (R)-4,5,6,7-Tetrahydro-2,6-benzothiazolodiamine | |
| 批号 (Batch No.): | 106092-11-9 | |
| 生产日期: (Manuf. Date): | C04-2110002 | |
| 复验期 (Retest Date): | 2021/10/12 | |
| 执行标准 (Specification): | 2023/09 | |
| 执行标准 (Specification): | 企业标准 (Enterprise Standard): QS-C04-01 | |
| 项目 (Item) | 标准 (Standard) | 结论 (Result) |
| 性状 (Description) | 白色或类白色粉末 (White or off-white powder) | 符合规定 (Conforms) |
| 含量 (Purity) | $\geq 99.0\%$ | 99.8% |
| e. e. % | $\geq 99.0\%$ | 99.9% |
| 对映异构体 (Isomer Assay) | $\leq 0.5\%$ | 0.05% |
| 旋光 (Specific Rotation) | $+96.0^\circ \sim +104.0^\circ$ (C=1.0, MeOH) | $+99.0^\circ$ |
| 有关物质 (Related substances) | $\leq 1.0\%$ | 0.2% |
| 炽灼残渣 (Residue on ignition) | $\leq 0.5\%$ | 0.1% |
| 水分 (Water K.F.) | $\leq 1.0\%$ | 0.2% |
| 结论 (Conclusion) | 本批产品符合企业标准 (The product conforms to Enterprise Standard): QS-C04-01 | |
| 储存 (Storage) | 密闭、避光 (Airtightness, Dark) | |

批准: 任建强

复核: 戚镇涛

分析: 冯静

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