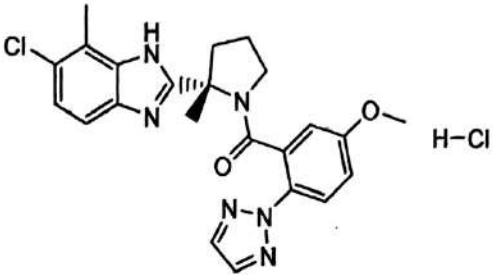


## 检验报告单

## CERTIFICATE OF ANALYSIS

|                                      |                                                                                                                                                                   |                                                                                                                                                                                                              |                      |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| 品名 Product Name:                     |                                                                                                                                                                   | 结构式 Structural formula:                                                                                                                                                                                      |                      |
| 盐酸达利雷生<br>Daridorexant Hydrochloride |                                                                                                                                                                   |                                                                                                                            |                      |
| CAS No.: 1792993-84-0                |                                                                                                                                                                   |                                                                                                                                                                                                              |                      |
| 批号 Batch No.: MS107101-260701        |                                                                                                                                                                   | 批量 Batch size: 5.11kg                                                                                                                                                                                        |                      |
| 生产日期 Mfg. Date: 2026.07.22           |                                                                                                                                                                   | 检验日期 Test Date: 2026.07.23                                                                                                                                                                                   |                      |
| 复验日期 Retest Date: 2028.07.21         |                                                                                                                                                                   | 检验标准 Test standard: QS-FP-107101-00                                                                                                                                                                          |                      |
| 检验项目<br>Test items                   | 标准<br>Specification                                                                                                                                               |                                                                                                                                                                                                              | 检验结果<br>Test results |
| 外观<br>Appearance                     | 白色至淡黄色粉末<br>White to light yellow powder                                                                                                                          |                                                                                                                                                                                                              | 白色粉末<br>White powder |
| 溶解度<br>Solubility                    | 本品在二甲亚砜、N,N-二甲基甲酰胺中溶解，在乙醇中略溶，在水中几乎不溶。<br>Soluble in dimethyl sulfoxide and N, N- dimethylformamide, sparingly soluble in ethanol, practically insoluble in water. |                                                                                                                                                                                                              | 符合<br>Complied       |
| 鉴别<br>Identification                 | HPLC                                                                                                                                                              | 在含量测定项下，供试品溶液主峰保留时间应与对照品溶液主峰保留时间一致。<br>The retention time of the major peak in the chromatogram of the sample solution should correspond to that of the standard solution as obtained in the test for Assay. | 符合<br>Complied       |
|                                      | IR                                                                                                                                                                | 供试品的红外光谱图应与对照品的一致。<br>The sample spectrum must match with the standard spectrum.                                                                                                                             | 符合<br>Complied       |
| 水分<br>Water                          | ≤ 1.0%                                                                                                                                                            |                                                                                                                                                                                                              | 0.09%                |
| 炽灼残渣<br>Residue on ignition          | ≤ 0.1%                                                                                                                                                            |                                                                                                                                                                                                              | 0.03%                |
| 重金属<br>Heavy metals                  | ≤ 20ppm                                                                                                                                                           |                                                                                                                                                                                                              | 符合<br>Complied       |
| 有关物质<br>Related substances           | 杂质 A<br>Impurity A                                                                                                                                                | ≤ 0.15%                                                                                                                                                                                                      | 0.01%                |
|                                      | 杂质 B<br>Impurity B                                                                                                                                                | ≤ 0.15%                                                                                                                                                                                                      | 未检出<br>N.D           |
|                                      | 杂质 C<br>Impurity C                                                                                                                                                | ≤ 0.15%                                                                                                                                                                                                      | 0.02%                |
|                                      | 单个未知杂质<br>Individual unspecified impurity                                                                                                                         | ≤ 0.10%                                                                                                                                                                                                      | 0.02%                |



|                           |                                                                                                                                              |          |            |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|----------|------------|
|                           | 总杂<br>Total impurities                                                                                                                       | ≤ 1.0%   | 0.08%      |
| 对映异构体<br>Enantiomer       | ≤ 0.15%                                                                                                                                      |          | 未检出<br>N.D |
| 残留溶剂<br>Residual solvents | 乙醇<br>Ethanol                                                                                                                                | ≤ 0.5%   | 未检出<br>N.D |
|                           | 异丙醇<br>Isopropanol                                                                                                                           | ≤ 0.5%   | 0.06%      |
|                           | 二氯甲烷<br>Dichloromethane                                                                                                                      | ≤ 0.06%  | 0.02%      |
|                           | 正己烷<br>n-hexane                                                                                                                              | ≤ 0.029% | 未检出<br>N.D |
|                           | 乙酸乙酯<br>Ethyl acetate                                                                                                                        | ≤ 0.5%   | 未检出<br>N.D |
|                           | 四氢呋喃<br>Tetrahydrofuran                                                                                                                      | ≤ 0.072% | 0.001%     |
| 含氯量<br>Chloride content   | 按无水物计, 应为 6.3%~8.3%。<br>6.3%~8.3% on anhydrous basis.                                                                                        |          | 7.0%       |
| 含量<br>Assay               | 按无水物计算, 含 $C_{23}H_{23}ClN_6O_2 \cdot HCl$ 应为 98.0%~102.0%。98.0%~102.0% of $C_{23}H_{23}ClN_6O_2 \cdot HCl$ , calculated on anhydrous basis. |          | 100.2%     |
| 结论<br>Conclusion          | 符合 QS-FP-107101-00 的标准要求。<br>The results comply with the QS-FP-107101-00.                                                                    |          |            |
| 储存条件<br>Storage condition | 常温密封保存。<br>Stored at room temperature with tight seal.                                                                                       |          |            |

报告人/日期:

Reported by/date

刘双  
2026.07.28

复核人/日期:

Reviewed by/date

R/S  
2026.07.28

批准人/日期:

Approved by/date

R/S  
2026.07.28