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## Certificate of Analysis 成品检验报告

|                                |                                |   |                   |   |                              |
|--------------------------------|--------------------------------|---|-------------------|---|------------------------------|
| Product<br>名称                  | Mefenamic Acid<br>甲芬那酸         |   | Mfg. Date<br>生产日期 | Jun. 11. 2021<br>2021年06月11日  |                              |
| Lot No.<br>批号                  | MFAR-2106315-A                 | Quantity<br>数量  | 950Kg             | Ret. Date<br>复验日期   | Jun. 10. 2026<br>2026年06月10日 |
| Testing Specifications<br>检验标准 |                                | USP43   |                   | Rep. Date<br>报告日期   | Jul. 28. 2021<br>2021年07月28日 |
| Testing Items<br>检验项目          |                                | Specifications<br>标准规定  |                   | Results<br>检验结果   |                              |
| 1.                             | Description 性状                 | White to off-white crystal powder<br>白色或类白色结晶粉末。  |                   | White crystal powder<br>白色结晶粉末  |                              |
| 2.                             | Identification A (IR)<br>红外吸收  | Conform to the reference standard<br>应与化学对照标准品图谱一致  |                   | Conform to the reference standard<br>与对照品图谱一致   |                              |
| 3.                             | Identification B (LC)<br>液相鉴别  | The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay<br>按含量项下检测, 主峰与对照品保留时间一致 |                   | The retention time of the major peak of the Sample solution corresponds to that of the Standard solution<br>样品的主峰保留时间与对照品一致 |                              |
| 4.                             | Loss on Drying 干燥失重            | ≤1.0%   |                   | 0.02%   |                              |
| 5.                             | Residue on Ignition 炽灼残渣       | ≤0.1%   |                   | 0.04%   |                              |
| 6.                             | Assay 含量<br>(dried basis 按干品计) | 98.0% ~ 102.0%  |                   | 99.9%   |                              |
| 7.                             | Organic Impurities<br>相关物质     | Any Impurity 单个未知杂质 ≤0.07%<br>Total impurity 总杂质 ≤0.5%  |                   | <0.03%<br><0.03%  |                              |
| 8.                             | Residual Solvents 残留溶剂         | Toluene 甲苯 ≤890ppm  |                   | 4ppm  |                              |
|                                |                                | DMF N,N 二甲基甲酰胺 ≤880ppm  |                   | 3ppm  |                              |
| Conclusion<br>结论               |                                | This product is tested according to the current STM-API-014, and the results comply with the requirements of USP43<br>本品按现行 STM-API-014 进行检测, 结果符合 USP43 要求 |                   |   |                              |

