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## 伽马环糊精检验报告

### COA for GAMMA CYCLODEXTRIN

CAS No.:17465-86-0

|                                                                                                                           |                     |                                                                                                                            |                                                                                                                                                                                 |                                      |
|---------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| 批号Batch No.                                                                                                               |                     | 20250208                                                                                                                   | 包装规格Packing                                                                                                                                                                     | 20kg/袋bag                            |
| 生产日期Manufacturing date                                                                                                    |                     | 2025.02.08                                                                                                                 | 数量Quantity                                                                                                                                                                      | 1000kg                               |
| 取样日期Sampling date                                                                                                         |                     | 2025.02.17                                                                                                                 | 报告日期Report Date                                                                                                                                                                 | 2025.02.26                           |
| 取样地点Place of sample                                                                                                       |                     | 洁净间Clean room                                                                                                              | 有效期至Expiry date                                                                                                                                                                 | 2027.02.07                           |
| 检验依据Test Standard                                                                                                         |                     | USP-NF2023                                                                                                                 |                                                                                                                                                                                 |                                      |
| 检验项目ITEMS                                                                                                                 |                     |                                                                                                                            | 标准CRITERIA                                                                                                                                                                      | 检验结果RESULTS                          |
| 性状Appearance                                                                                                              |                     |                                                                                                                            | 本品为白色或类白色无定形粉末或结晶性粉末；易溶于水和丙二醇；微溶于酒精。<br>White or almost white,amorphous or crystalline powder.Freely soluble in water and in propylene glycol;very slightly soluble in alcohol. | 白色结晶性粉末<br>White crystalline powder. |
| 鉴别Identification                                                                                                          | 红外光谱IR              | 与标准样品呈现相同的吸收带。<br>Same absorption bands as USP Gamma Cyclodextrin RS.                                                      |                                                                                                                                                                                 | 符合Conform                            |
|                                                                                                                           | 液相HPLC              | 供试品溶液主峰的保留时间应与标准溶液的保留时间一致。<br>The retention time of the major peak of sample solution corresponds to the standard solution |                                                                                                                                                                                 | 符合Conform                            |
|                                                                                                                           | 旋光度Optical rotation | +174°~+180°                                                                                                                |                                                                                                                                                                                 | +176°                                |
| 炽灼残渣Residue on ignition                                                                                                   |                     |                                                                                                                            | ≤0.1%                                                                                                                                                                           | 0.04%                                |
| 还原物质Reducing Substances                                                                                                   |                     |                                                                                                                            | ≤0.5%                                                                                                                                                                           | 符合Conform                            |
| 阿尔法环糊精Alpha Cyclodextrin                                                                                                  |                     |                                                                                                                            | ≤0.5%                                                                                                                                                                           | 未检出Not detected                      |
| 倍他环糊精Beta Cyclodextrin                                                                                                    |                     |                                                                                                                            | ≤0.5%                                                                                                                                                                           | 未检出Not detected                      |
| 其他杂质Sum Of Other Lmpurities                                                                                               |                     |                                                                                                                            | ≤0.5%                                                                                                                                                                           | 未检出Not detected                      |
| 干燥失重Loss on drying                                                                                                        |                     |                                                                                                                            | ≤11.0%                                                                                                                                                                          | 8.8%                                 |
| 溶液澄清晰度与颜色Color and clarity of solution                                                                                    |                     |                                                                                                                            | 在420nm吸光度不大于0.20,溶液澄清。<br>At 420 nm,the absorbance is not greater than 0.20,and the solution is clear.                                                                          | 符合Conform                            |
| 含量Assay                                                                                                                   |                     |                                                                                                                            | 98.0%~102.0%                                                                                                                                                                    | 99.9%                                |
| 需氧菌总数The total aerobic microbial count                                                                                    |                     |                                                                                                                            | ≤1000cfu/g                                                                                                                                                                      | <10cfu/g                             |
| 霉菌、酵母菌总数<br>The total combined moulds and yeasts count                                                                    |                     |                                                                                                                            | ≤100cfu/g                                                                                                                                                                       | <10cfu/g                             |
| 贮藏Packaging and storage                                                                                                   |                     |                                                                                                                            | 密封，在干燥处保存<br>Preserve in well-closed containers.Store at room temperature,                                                                                                      |                                      |
| 结论Conclusion:本品符合USP-NF2023标准 ConpáthebsP-NF2023.                                                                         |                     |                                                                                                                            |                                                                                                                                                                                 |                                      |
| 检验人Laboratorian: 郭守宇  审核人Verifier: 方家 |                     |                                                                                                                            |                                                                                                                                                                                 |                                      |

