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# HUNAN DONGTING PHARMACEUTICAL CO., LTD.
# 湖 南 洞 庭 药 业 股 份 有 限 公 司

## CERTIFICATE OF ANALYSIS
## 检验报告书

报告书编号 COA No.: 2021040361　　记录控制码 Record Control Code: 21110651

| | | | |
|---|---|---|---|
| 品 名<br>Product Name | 氨甲环酸<br>Tranexamic acid | 取样件数及数量<br>Drums Sampled & Sample Qty. | 7 桶/ Drums　625g |
| 批 号<br>Batch No. | X2104016M | 收检日期<br>Date Sample Received | 2021.04.16 |
| 包装/数量<br>Drums/Qty. | 782.6Kg　33 桶/Drums | 报告日期<br>COA Issuing Date | 2021.04.23 |
| 检验项目<br>Test Items | 全 检<br>All items | 生产日期<br>Mfg. Date | 2021.03.21 |
| 质量标准<br>Quality Specification | CEP & ZLBZ/K023-9 | 复验期<br>Retest Date | 2023.03.20 |

| 检测项目<br>**Items of Test** | | 法定接受标准<br>**Pharmacopeial Criteria** | 检测结果<br>**Test Result** |
|---|---|---|---|
| 性状<br>**CHARACTERS** | | 外观:白色或类白色结晶性粉末<br>*Appearance:* White or almost white, crystalline powder | 白色结晶性粉末<br>White crystalline powder |
| | | 溶解性:易溶于水与冰醋酸,不溶于丙酮与乙醇(96%)<br>*Solubility:* Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and in ethanol (96%) | / |
| 鉴别<br>**IDENTIFICATION** | | 红外吸收光谱*(2.2.24)*:与氨甲环酸对照品一致<br>*Infrared Absorption Spectrophotometry:* IR spectrum is in concordance with Tranexamic acid CRS | 合格<br>Pass |
| **检查 TEST** | pH *(2.2.3)* | 7.0 ～ 8.0 | 7.4 |
| | 有关物质<br>*(HPLC 2.2.29)*<br>Related Substances<br>*(HPLC2.2.29)* | 杂质 B/ Impurity B≤ 0.15% | 0.05% |
| | | 杂质 C/ Impurity C≤ 0.05% | 0.001% |
| | | 杂质 D/ Impurity D≤ 0.05% | 0.0002% |
| | | 杂质 E/ Impurity E≤ 0.05% | 0.003% |
| | | 杂质F/ Impurity F≤ 0.05% | 0.001% |
| | | 未指定杂质/Unspecified impurities≤ 0.05% | 未检出/Not Detected |
| | | 总杂质/Total impurities≤ 0.2% | 0.06% |
| | 卤化物*(2.4.4)*<br>Halides Expressed as Chlorides | ≤ 140ppm | <140ppm |
| | 干燥失重 *(2.2.32)*<br>Loss on Drying | ≤ 0.5% | 0.040% |
| | 硫酸灰分*(2.4.14)*<br>Sulphated Ash | ≤ 0.1% | 0.013% |
| 含量/ASSAY<br>(Titration *2.2.20*) | | 按干品计含 $C_8H_{15}NO_2$ 应为 99.0% ～ 101.0%<br>Should be within (Dried based) 99.0% ～101.0% | 100.2% |

结论:本批产品按《CEP & ZLBZ/K023-9》检验，结果符合规定。
**CONCLUSION**: the batch complies with the prescribed specification above as per CEP & ZLBZ/K023-9。

QC: 宋波 2021.04.23　　QA: 王女肖 2021.04.23

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