



HUNAN DONGTING PHARMACEUTICAL CO., LTD.
湖南洞庭药业股份有限公司

CERTIFICATE OF ANALYSIS

报告书编号 COA No.: 2018100034

样品控制编号 Sample Control Code: 18111836

品名 Product Name	氨甲环酸 Tranexamic acid	取样件数及重量 Drums Sampled & Sample Qty.	7 桶: Drums 350g
批号 Batch No.	X1809021M	收检日期 Date Sample Received	2018.09.29
包装/数量 Drums/Qty.	880.5Kg 37 桶: Drums	报告日期 COA Issuing Date	2018.10.06
检验项目 Test Items	全检 All items	生产日期 Mfg. Date	2018.09.22
质量标准 Quality Specification	CEP & ZLBZ/K023-7	复验期 Re-test Date	2020.09.21

检测项目 Items of Test	法定接受标准 Pharmacopeial Criteria	检测结果 Test Result
性状 CHARACTERS	外观: 白色或类白色结晶性粉末 Appearance: White or almost white, crystalline powder	白色结晶性粉末 White crystalline powder
	溶解性: 易溶于水与冰醋酸, 不溶于丙酮与乙醇 (96%) Solubility: Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and in ethanol (96%)	合格 Pass
鉴别 IDENTIFICATION	红外吸收光谱 (2.2.4): 与氨甲环酸对照品一致 Infrared Absorption Spectrophotometry: IR spectrum is in concordance with Tranexamic acid CRS	合格 Pass
检查 TEST	pH (2.2.3)	7.0 ~ 8.0
	杂质 A / Impurity A	未检出 / Not Detected
	杂质 B / Impurity B	0.05%
	杂质 C / Impurity C	0.001%
	杂质 D / Impurity D	0.002%
	其它杂质 / Other Impurities	未检出 / Not Detected
	未指定杂质总量 ≤ 0.2% Sum of unspecified impurities: 0.2%	0.002%
卤化物 (2.4.4) Halides Expressed as Chlorides	≤ 140ppm	< 140ppm
干燥失重 (2.2.32) Loss on Drying	≤ 0.5%	0.088%
硫酸灰分 (2.4.14) Sulphated Ash	≤ 0.1%	0.042%
含量 / ASSAY (Titration 2.2.29)	按干品计含 C ₁₁ H ₁₇ NO ₂ 应为 99.0% ~ 101.0% Should be within (Dried based) 99.0% ~ 101.0%	99.6%

结论: 本批产品按《CEP & ZLBZ/K023-7》检验, 结果符合规定。

CONCLUSION: the batch complies with the prescribed specification above as per CEP & ZLBZ/K023-7

QC: 2018.10.08

QA: 王娟 2018.10.08

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法定标准页
Pharmacopeial Specification