



CERTIFICATE OF ANALYSIS

检验报告书

报告书编号 COA No.: 2020100514

记录控制码 Record Control Code: 20112017

品名 Product Name	氨甲环酸 Tranexamic acid	取样件数及数量 Drums Sampled & Sample Qty.	7 桶/ Drums 255g
批号 Batch No.	X2010028M	收检日期 Date Sample Received	2020.10.24
包装/数量 Drums/Qty.	901.2Kg 36 桶/Drums	报告日期 COA Issuing Date	2020.10.31
检验项目 Test Items	全检 All items	生产日期 Mfg. Date	2020.10.18
质量标准 Quality Specification	CEP & ZLBZ/K023-8	复验期 Retest Date	2022.10.17

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 <i>Appearance: White or almost white, crystalline powder</i>	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%) <i>Solubility: Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and in ethanol (96%)</i>	/
鉴别 IDENTIFICATION	红外吸收光谱(2.2.24):与氨甲环酸对照品一致 <i>Infrared Absorption Spectrophotometry: IR spectrum is in concordance with Tranexamic acid CRS</i>	合格 Pass
检查 TEST	pH (2.2.3)	7.0 ~ 8.0
	有关物质 (HPLC 2.2.29) Related Substances (HPLC 2.2.29)	杂质 B/ Impurity B ≤ 0.15%
		杂质 C/ Impurity C ≤ 0.05%
		杂质 D/ Impurity D ≤ 0.05%
		杂质 E/ Impurity E ≤ 0.05%
		杂质 F/ Impurity F ≤ 0.05%
		未指定杂质/Unspecified impurities ≤ 0.05%
		总杂质/Total impurities ≤ 0.2%
	卤化物 (2.4.4) Halides Expressed as Chlorides	≤ 140ppm
	干燥失重 (2.2.32) Loss on Drying	≤ 0.5%
	硫酸灰分 (2.4.14) Sulphated Ash	≤ 0.1%
含量/ASSAY (Titration 2.2.20)	按干品计含 C ₈ H ₁₅ NO ₂ 应为 99.0% ~ 101.0% Should be within (Dried based) 99.0% ~ 101.0%	100.0%

结论:本批产品按《CEP & ZLBZ/K023-8》检验,结果符合规定。

CONCLUSION: the batch complies with the prescribed specification above as per CEP & ZLBZ/K023-8.

QC: 何芳 2020.11.01

QA: 王娟 2020.11.02