



**XI'AN CORE PURE BIO&TECH CO., LTD.**  
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## **CERTIFICATE OF ANALYSIS**

<b>Product Name:</b> 品名	<b>Tranexamic acid 氨甲环酸</b>		
<b>Batch Number:</b> 批号	101-2007006-1	<b>Manu. Date:</b> 生产日期	2020.07.16
<b>Quantity:</b> 数量	500.0KGS	<b>Expiration Date:</b> 保质期	2023.07.15
<b>Report Date:</b> 报告日期	2020.07.16	<b>Test items:</b> 检测项目	All items 全检
<b>Quality specification :</b> 检验依据	British Pharmacopoeia 2013		

<b>Items</b> 项目	<b>Specification</b> 标准规定	<b>Results</b> 检验结果
Description 性状	White Crystals or crystalline powder, odorless 白色结晶性粉末	White crystalline powder 白色结晶性粉末
Identification 鉴别	Correspond to Tranexamic acid CRS 红外 IR: 与氨甲环酸对照图谱一致	Pass 合格
Ph 碱度	7.0-8.0	7.56
Solubility 溶解度	Free soluble in water and in glacial acetic acid, practically insoluble in acetone and inethanol(96%) 易溶于水和冰醋酸, 几乎不溶于 丙酮和乙醇 (96%)	Pass 合格
Chlorides 氯化物	≤140 ppm	Pass 合格
Heavy metals 重金属	≤10ppm	<10ppm
Related substances 相关物质	Impurity A ≤0.10%	0.07%
	Impurity B ≤0.20%	0.11%
	Impurity C ≤0.10%	0.01%
	Impurity D ≤0.10%	0.01%
	Unspecified impurities ≤0.10% 未知最大单杂	0.01%
	Sum of unspecified impurities ≤0.20% 未知单杂 之和	Not detective/未检出
Loss on drying 干燥失重	≤0.5% (ig.105℃, 2hours)	0.20%
Sulfated ash 灼烧残渣	≤0.1%	0.01%
Assay/含量	Not less than (Dry based) 99.0%~101.0% 按干品计应为 99.0%~101.0%	99.8%
Conclusion 结论	The batch complies with the prescribed specification above as per BP2013 本批次按照 BP2013 检验, 结果符合规定。	

**Storage:** Store in tight, light-resistant containers, avoid exposure to direct sunlight, moisture and excessive heat.

**Shelf Life:** 36 months if store under the conditions above and stay in original packaging.

**QC:** Frank Yao

**Checker:** Simon He