

## 产品质量检验报告单

## Certificate of Analysis

<b>产品名称</b> Product Name	氨甲环酸 Tranexamic Acid	
<b>CAS 号</b> CAS Number	1197-18-8	
<b>生产批号</b> Batch Number	XT-250720-1B	英维沃化工科技（广州）有限公司
<b>生产日期</b> Product Date	2025-07-20	InvivoChem (Guangzhou) Co. Ltd
<b>产品数量</b> Product Quantity	375kg	www.invivochem.cn; 020-31522723
<b>检测标准</b> Inspection Standard	中国药典2020 ChP2020	
<b>检验日期</b> Inspection Date	2025-07-20	
<b>复检日期</b> Re-inspection Date	2030-06-19	

检验项目 Inspection Items	规格指标 Specification Standards	检验结果 Test Results
性状 Appearance	白色结晶或结晶性粉末；无臭 White crystalline or crystalline powder, odorless 易溶于水，在乙醇、丙酮、三氯甲烷或乙醚中几乎不溶 Soluble in water, almost insoluble in ethanol, acetone, chloroform or ether	符合 Corresponds
鉴别 Identification	红外吸收图谱应与对照的红外吸收图谱一致 Correspond to the reference spectrum of Tranexamic acid 茛三酮显色呈蓝紫色 t appears bluish-purple after tinting with ninhydrin	符合 Corresponds
pH	7.0-8.0	7.5
溶液澄清度与颜色 Clarity and color of solution	1.0g/20mL水溶液：溶液应澄清无色 1.0g/20ml aqueous solution: clear and colorless	符合 Corresponds
氯化物 Chloride	≤0.014%	符合 Corresponds
硫酸盐 sulfate	≤0.07%	符合 Corresponds
钡盐 Barium salt	1.0g/20mL水溶液：分为两份各加1mL水和稀硫酸，应同样澄清 1.0g/20mL aqueous solution is divided into two parts with 1mL water and dilute sulfuric acid, and the solution should be equally clear	符合 Corresponds
重金属 Heavy metals	≤10ppm	符合 Corresponds
有关物质 (LC) Related substance	杂质1/mpurity1: RRT1.2 ≤ 0.1% 杂质2/mpurity2: RRT1.5 ≤ 0.2% 其他单个杂质/Each other impurity ≤ 0.1% 总杂质/Total Impurities ≤ 0.5%	未检出/Not detected 0.02% 0.06% 0.10%
纯度 (LC) Purity	≥99.0%	99.90%
易炭化物 Readily carbonizable substance	与橙黄色0.5号标准比色液比较，不得更深 Compared with orange yellow 0.5 standard colorimetric solution, not deeper	符合 Corresponds
干燥失重 Loss on drying	≤0.5%	0.1%
炽灼残渣 Residue on ignition	≤0.1%	0.07%
含量 (滴定) Assay	99.0-101.0%	99.4%
<b>结论</b> Conclusion	本批产品按《中国药典2020版》检验，结果符合规定 The batch complies with the prescribed specification above as per ChP2020	

检验 Inspector	检1	复核 Supervisor	检2
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