



### Certificate of Analysis

Product Name	Batch No.	Quantity	Date of production	Term of validity
TRANEXAMIC ACID	20200410	500KG	2020.4.10	2025/4/11
Item	Standard		Results	
Characteristics	White or almost white, crystalline powder		White crystalline powder	
Solubility	Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and 96% alcohol		Complies	
Identification	Infrared absorption atlas consistent with the contrast atlas		Complies	
Clarity and color	Solution should clarify and colorless		Complies	
PH	7.0~8.0		7.6	
Related substances Liquid chromatography (2.2.29)	Impurity A: $\leq 0.1\%$ Impurity B: $\leq 0.2\%$ Any other impurity : $\leq 0.1\%$ All other impurity : $\leq 0.2\%$		0.047% 0.098% $< 0.025\%$ $< 0.025\%$	
Chlorides	$\leq 140\text{ppm}$		$< 140\text{ppm}$	
Heavy Metals	$\leq 10\text{ppm}$		$< 10\text{ppm}$	
Loss on drying	$\leq 0.5\%$		0.2%	
Sulphated Ash	$\leq 0.1\%$		0.03%	
Assay	99.0%~101.0%		99.7%	
Bacterial Count	$\leq 10\text{CFU/G}$		$< 10\text{CFU/G}$	
Mold and Yeast	$\leq 10\text{CFU/G}$		$< 10\text{CFU/G}$	
Conclusion	Complies with <b>BP2017</b> specification.			
Analyst	Lei xu	Check	Yabin Song	