

CERTIFICATE OF ANALYSIS

Product Name:	Hydrocortisone Acetate		
Batch No.	HA-220701	Quantity	1kg
Manufacturing Date	July 28, 2022	Expiry Date	July 27, 2025
Specification	USP41		
Analytical Results			
Items	Specifications		Results
Appearance	White or almost white crystalline powder		Almost white crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in ethanol and in methylene chloride		Complies
Identification (A,B)	A:IR: B:UV		Complies
Specific optical rotation	+158°~+167°		+166°
Loss on drying	≤1.0%		0.14%
Residue on ignition	≤0.5%		0.10%
Related substances	Any individual impurity: ≤1.0%		0.28%
	Total impurity: ≤2.0%		0.76%
Residual Solvent	Methanol ≤3000ppm		Complies
	Dichloromethane ≤600ppm		Complies
	Acetone≤5000ppm		Complies
	N,N-Dimethylformamide≤880ppm		Complies
	Tetrahydrofuran≤720ppm		Complies
Assay	97.0%~102.0%		99.2%
Particle Size	90% < 30um		Complies
Packaging and storage	Preserve in tight, light-resistant containers.		
Conclusion	The test product complies with the requirements of USP41.		

Inspector: Carlifor Wu

Verifier: Jack He

