

CERTIFICATE OF ANALYSIS

Product Name:	Amisulpride		
Batch No.	210402		
CAS No.	71675-85-9	Test Date	April 10, 2021
Manufacturing Date	April 9, 2021	Expiry Date	April 8, 2023
Quantity	50 KG	Reference Spec.	EP7.0
Analytical Results			
Items	Specifications		Results
Characters	White or almost white crystalline powder		Complies
Solubility	Practically insoluble in water, freely soluble in methylene chloride, sparingly in ethanol		Complies
Identification	IR		Complies
Melting point	About 126°C		125.5°C
Appearance of solution	Meet the requirements		Complies
Specific optical rotation	-0.10°~+0.10°		0
Impurity A	≤0.1%		Complies
Related substances	Single impurity: ≤0.1%		0.09%
	Total impurity: ≤0.3%		0.18%
Residue on ignition	≤0.1%		0.09%
Chloride	≤200ppm		Complies
Heavy metals	≤10ppm		Complies
Loss on drying (100~105°C)	≤0.5%		0.37%
Assay	99.0%~101.0%(on dried basis)		99.82%
Conclusion	The product comply with the requirements of EP7.0		

Inspector: Carlifor Wu

Verifier: Jack He