

CERTIFICATE OF ANALYSIS

Product Name:	Clozapine		
Batch No.	Clo-20231128-08-A	Batch Quantity	255.4Kg
Manufacturing Date	November 28, 2023	Expiry Date TO	November 27, 2026
Packing Size	25Kg/Drum		
Analytical results			
Items	Specifications		Results
Characteristics	Yellow, crystalline powder		Yellow, crystalline powder
	Solubility: practically insoluble in water, freely soluble in methylene chloride, soluble in ethanol(96%). It dissolves in dilute acetic acid		Conform
Identification	A. Melting Point: 182°C to 186°C		184°C
	B.IR Spectrum: Corresponds to that of the standard		Complies
Loss on Drying	≤0.5%		0.05%
Sulphated Ash	≤0.1%		0.04%
Heavy Metals	≤20ppm		<20ppm
Residual Solvents by GC	Ethanol: ≤1000ppm		284ppm
	Toluene: ≤890ppm		5ppm
Related Substances by HPLC	Impurity A≤0.1%		<0.05%
	Impurity B≤0.2%		<0.05%
	Impurity C≤0.3%		<0.05%
	Impurity D≤0.2%		<0.05%
	Single unspecified impurity≤0.10%		0.06%
	Total impurities≤0.6%		0.06%
Assay by titration (on the dried basis)	99.0%to 101.0%		99.90%
Particle size	D(90)≤470μm		252μm
Microbiological test	TAMC≤1000cfu/g		<10cfu/g
	TYMC≤100cfu/g		<10cfu/g
	Absence of Escherichia coli(1g)		Complies
Conclusion	This batch complies with Specification		

Inspector: Carlifor Wu

Verifier: Jack He

