

No.: BPAP-614-A-00/3.0

CERTIFICATE OF ANALYSIS

Product Name	Mildronate Dihydrate	CAS No.	76144-81-5
Batch No.	P010661420A	Mfg. Date	Jun. 07, 2020
Quantity	500kg	Retest Date	Jun. 06, 2022
Packing	25kg/Drum	Report Date	Jun. 12, 2020
Specification	Oral Grade		

ITEM	SPECIFICATION	RESULT
Appearance	White or almost white crystalline powder	Complies
Identification	A) Should be positive respond IR: Conforms to the reference standard	Complies
Solubility	Freely soluble in water, soluble in 95% Ethanol	Complies
pH	7.0~9.0	8.16
Clarity	Should be not deeper than working standard solution	Complies
Color	Should be lighter than the standard solution	Complies
Optical Transmission	≥95%	99.2%
Water	19.0%~21.0%	20.10%
Chlorides	≤0.01%	Complies
Sulfates	≤0.05%	Complies
Sulfated Ash	≤0.1%	Complies
Heavy Metals	≤10ppm	Complies
Assay(Titration)	99.0% ~ 101.0%	99.95%
Related Substances		
Any Individual Impurity	≤0.3%	0.04%
Total Impurities	≤1.0%	0.08%
Residual Solvents		
Methanol	≤3000ppm	Complies
Ethanol	≤5000ppm	Complies
Microbiological	Should meet the requirements	Complies
Bacterial Endotoxins	≤0.35IU/mg	Complies
Conclusion	Comply with the specification.	
Storage	Preserve in tight containers, protected from strong light and high heat.	

Analyst:

Reviewed by:

Approved by: