

CERTIFICATE OF ANALYSIS

Product Name:	Carbidopa		
Batch No.	C02-20230304	Specifications	EP10
Manufacturing Date	March 1, 2023	Expiry Date TO	February 28, 2026
Quantities/Spec.	251.34kg/25kg/drum	Report Date	April 4, 2023
Test Basis	SOP-FP-005-12	Report No.	C02-2023001(EP)
Analytical results			
Items	Specifications		Results
Appearance	White or yellowish white powder		Yellowish white powder
Solubility	Slightly soluble in water; very Slightly soluble in ethanol(96percent); practically insoluble in methylene chloride.it dissolves in dilute solutions of mineral acids		Meets the requirements
Identification	A、 Specific optical rotation: Complies with specific optical rotation test		Complies
	C、 IR: The spectrum of sample complies with the spectrum obtained with standard		Complies
Appearance of solution	Clear and not more than reference solution BY6 or B6		Clear and less than BY6
Specific optical rotation	-22.5°~-26.5°(Dried substance)		-24.0°
Hydrazine	Not more than 20ppm		Less than 20ppm
Loss on drying	6.9%~7.9%		7.50%
Sulphated ash	Not more than 0.1%		0.02%
Assay	98.5%~101.0%		99.80%
Impurity A	Not more than 0.5%		0.24%
Impurity J	Not more than 0.25%		0.10%
Impurity D+E	Not more than 0.2%		0.11%
Impurity F	Not more than 0.15%		Not detected
Impurity H	Not more than 0.15%		0.01%
Impurity I	Not more than 0.16%		Not detected
Unspecified impurity	Not more than 0.10%		0.02%
Total impurities	Not more than 1.0%		0.50%
Residual Solvents	Methanol: Not more than 3000ppm		Below LOD
	2-Propanol: Not more than 5000ppm		Below LOD
	Chloroform:Not more than 60ppm		Below LOD
	Benzene:Not more than 2ppm		Below LOD
	Toluene: Not more than 890ppm		Below LOD
	Cyclohexanone: Not more than 20ppm		Below LOD
Conclusion	The batch complies with the EP10 Specifications.		

Inspector: Carlifor Wu

Verifier: Jack He