

Certificate of Analysis

Product Name	Levodopa	Batch No.	20201204
Mfg. Date	04/12/2020	Retest Date	03/12/2022
Quantity	1000kg	Reference	USP
Test Items	Specifications		Results
Appearance	White to off-white powder		Off-white powder
Solubility	Slightly soluble in water, practically insoluble in ethanol(96%).Freely soluble in 1M hydrochloric acid and sparingly soluble in 0.1M hydrochloric acid.		Conforms
Identification	Infrared absorption spectrum corresponds to the spectrum obtained with the RS.		Conforms
Appearance of solution	The solution is not more intensely coloured than reference solution BY6		Conforms
pH	4.5~7.0		5.8
Loss on drying	≤1.0%		0.38%
Sulfated ash	≤0.1%		0.06%
Heavy metals	≤10ppm		Conforms
Enantiomeric(HPLC)	Impurity D≤0.5%		N.D
Related substances (HPLC)	Impurity A≤0.1%		0.01%
	Impurity B≤0.5%		0.01%
	Impurity C≤0.2%		N.D
	Any unspecified impurity≤0.05%		0.01%
	Total impurities≤1.0%		0.05%
Assay (HPLC)	99.0%~101.0%(Calculated on anhydrous basis)		99.30%
Conclusion:	Complies with USP standard		

Analyst: David Yan

