

Certificate of Analysis Spironolactone

CAS No.	52-01-7	Code	BIOJSPR001
Batch No	C006-20240503	Manufacture Date	Jun.27, 2024
Retest Date	Jun.26, 2027	Quantity	25Kgs

Testing Items	Specifications	Results
Appearance	White or yellowish-white powder	White powder
Identification	The spectrum of the tested magenta is same as that of reference	Complies
Solubility	Very slightly soluble in water, soluble in ethanol (96%) and in methanol, sparingly soluble in acetone, slightly soluble in methylene chloride	Complies
Loss on Drying	≤0.5%	0.26%
Specific rotation	Between -41 °to -46 °	-42.7 °
Sulfated ash	≤0.1%	0.04%
Related substances	Impurity I \leq 0.5% Impurity E & F \leq 0.3% Impurity A & C \leq 0.2% Impurity D \leq 0.15% Unspecified impurity \leq 0.1% Total impurities \leq 0.7%	Not detected E: 0.01%; F: 0.08% A: 0.005%; C: Not detected 0.05% 0.07% 0.20%
Ordinary impurities	≤2.0%	Complies
Particle size	90%<25um	Complies
Residual solvent	DMF≤880ppm Methanol≤3000ppm	Not detected 14ppm
Assay	97.5%~103.0% (Calculated on the dried basis)	101.3%
Chromium	≤50ppm	Complies
Free mercapto compounds	≤0.1ml	Complies
Free thiol compounds	Should be conforms	Complies
Conclusion	This product conforms to EP10/USP43 star	ndard

^{*}Storage Condition: Store below 25°C, Protect from moisture and light.

