

Certificate of analysis

Spironolactone

CAS No.	52-01-7	Code	BIOJSPR001
Batch No	C006-20230812	Manufacture Date	Aug.25, 2023
Retest Date	Aug.24, 2026	Quantity	25Kg

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%	0.16%
Specific rotation	Between -41 ° to -46 °	-44.0 °
Sulfated ash	≤0.1%	0.04%
Related substances	Impurity I ≤0.5% Impurity E & F ≤0.3% Impurity A & C ≤0.2% Impurity D ≤0.15% Unspecified impurity ≤0.1% Total impurities ≤0.7%	<0.05% E: 0.01% ; F: 0.06% A: <0.05% ; C: <0.05% <0.05% 0.05% 0.05%
Ordinary impurities	≤2.0%	Complies
Particle size	100% pass 60 mesh	Complies
Residual solvent	DMF ≤880ppm Methanol ≤3000ppm	Not detected 13ppm
Assay	97.5%~103.0% (Calculated on the dried basis)	100.7%
Chromium	≤50ppm	Complies
Free mercapto compounds	≤0.1ml	Complies
Free thiol compounds	Should be conforms	Complies
Conclusion	This product conforms to EP10/USP43 standard	

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