

Certificate of Analysis

Spironolactone

CAS No.	52-01-7	Code	BIOJSPR001
Batch No	C006-20241118	Manufacture Date	Nov.28, 2024
Retest Date	Nov.27, 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	$\leq 0.5\%$	0.19%
Specific rotation	Between -41° to -46°	-43.7°
Sulfated ash	$\leq 0.1\%$	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: $< 0.05\%$; F: $< 0.05\%$ A: $< 0.05\%$; C: $< 0.05\%$ $< 0.05\%$ 0.06% 0.06%
Ordinary impurities	$\leq 2.0\%$	Complies
Particle size	90% $< 25\mu\text{m}$	Complies
Residual solvent	DMF $\leq 880\text{ppm}$ Methanol $\leq 3000\text{ppm}$	Not detected 12ppm
Assay	97.5%~103.0% (Calculated on the dried basis)	100.2%
Chromium	$\leq 50\text{ppm}$	Complies
Free mercapto compounds	$\leq 0.1\text{ml}$	Complies
Free thiol compounds	Should be conforms	Complies
Conclusion	This product conforms to EP11.0/USP43 standard	

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