

# Certificate of Analysis

## Sirolimus

CAS No.	53123-88-9	Code	BIOJSRL001
Batch No	250322	Manufacture Date	Mar.22, 2025
Retest Date	Mar.21, 2028	Quantity	5G

Testing Items	Specifications	Results
Appearance	White or off-white crystalline powder	Off-white powder
Specific rotation (on anhydrous basis)	-147° ~ -157°	-153°
Identification	HPLC: The retention time of major peak of test solution should correspond to that of comparison solution	Complies
	IR: Spectrum of test sample should confirm to that of reference standard spectrum	Complies
Related substances	Isomer A ≤ 1.0%	<0.01%
	Isomer C ≤ 5.0%	1.5%
	RRT0.86 ≤ 0.40%	0.24%
	RRT0.94 ≤ 0.15%	0.04%
	RRT1.06 ≤ 0.15%	0.02%
	Any other individual impurity ≤ 0.15%	0.10%
	Total impurities(Excluding A & C isomers) ≤ 2.0%	0.48%
Residual solvents	Methanol ≤ 3000ppm	19ppm
	Acetone ≤ 5000ppm	Not detected
	Dichloromethane ≤ 600ppm	Not detected
	Trans-1,2-Dichloroethylene ≤ 187ppm	Not detected
	N-hexane ≤ 290ppm	Not detected
	Ethyl acetate ≤ 5000ppm	Not detected
	n-Heptane ≤ 5000ppm	40ppm
	Butyl acetate ≤ 500ppm	Not detected
Water	≤ 1.0%	0.16%
Residue on ignition	≤ 0.15%	0.02%
Heavy metals	≤ 20ppm	<20ppm
Assay	98.0~102.0% (Calculated isomer B & C, on anhydrous basis)	99.3%
Conclusion	This product conforms to In-house standard	

**\*Storage condition: Store between 2°C~8°C, Protect from moisture and light.**