



Certificate of Analysis

Product name	Rivaroxaban Powder	Manufacture date	Mar.05.2024
Batch number	SW240305	Analysis date	Mar.06.2024
Batch quantity	100kg	Expiry date	Mar.05.2026

ANALYSIS	SPECIFICATION	RESULT
Assay	≥99%	99.9%
Appearance	White powder	Complies
Residue on ignition	≤0.1%	0.03%
Related substances	Any other impurity ≤0.2%	0.1%
	Total of impurity ≤0.5%	0.19%
Loss on drying	≤1.0%	0.13%
Heavy metal	≤20ppm	Complies
Related substances(by HPLC)	Any individual impurity ≤1.5%	0.28%
	Total impurities ≤2.0%	0.62%
Residual solvents	Ethanol ≤5000ppm	69ppm
	Methylene chloride ≤600ppm	43ppm
	Hexa ≤290ppm	Undetected (LOD 3ppm)
	Diox ≤380ppm	Undetected (LOD 8ppm)
	Pyridi ≤200ppm	Undetected (LOD 4ppm)
Conclusion	Conforming with enterprise specification	

Packing description:	Sealed export grade drum & double of sealed plastic bag
Storage:	Store in cool & dry place, keep away from strong light and heat
Shelf life:	2 years when properly stored

Quality Assurance Officer: 李强

Corrector: 佟丽华

Analyst: 靳琼

