



Certificate of Analysis

Product name	Roflumilast	Manufacture date	Oct.26.2024
Batch number	SW241026	Analysis date	Oct.27.2024
Batch quantity	100kg	Expiry date	Oct.26.2026

Items	Specification	Results
Appearance	White to off white powder	Complies
Identification	By IR	Complies
	By HPLC	Complies
Solubility	DMSO: soluble 20mg/mL, clear	Complies
Melting point	158 °C	94-95 °C
Residual solvents	Dichloromethane: ≤ 100ppm	Complies
	Hexane ≤ 200 ppm	Not detectable
	Ethyl acetate ≤ 500 ppm	Complies
	Tetrahydrofuran ≤ 100 ppm	Not detectable
Related substances	Impurity A: ≤ 0.10%	Complies
	Impurity B: ≤ 0.10%	Complies
	Any other single impurity ≤ 0.10%	Not detectable
	Total impurities ≤ 0.50%	99.34%
Assay	98.0-102.0%	99.45%

Packing description:	Sealed export grade drum & double of sealed plastic bag
Storage:	Store in cool & dry place not freeze., keep away from strong light and heat
Shelf life:	2 years when properly stored

Quality Assurance Officer: 李强

Corrector: 佟丽华

Analyst: 方锦

