



Certificate of Analysis

Product name	Linaclotide	Manufacture date	Feb.02.2026
Batch number	SW260202	Analysis date	Feb.03.2026
Batch quantity	100kg	Expiry date	Feb.02.2028

Item	Specification	Result
Appearance	White to off-white powder	Conforms
Specification	≥98%	98.4%
Melting Point	233°C	Conforms
Heavy metals	≤20ppm	Conforms
Solubility	Slightly soluble in water and sodium chloride solution (0.9%) DMF: 30 mg/ml DMSO:30 mg/ml DMSO:PBS(pH 7.2) (1:4): 0.20mg/ml	Conforms
		Conforms
		Conforms
		Conforms
Total Impurities	≤0.2%	0.13%
Ash content	≤0.1%	0.02%
Conclusion	Conforming to Enterprise Standard	

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: 陈琼

