



Certificate of Analysis

Product name	Ertugliflozin	Manufacture date	Jul.12.2025
Batch number	SW250712	Analysis date	Jul.13.2025
Batch quantity	500kg	Expiry date	Jul.12.2027

Item	Specification	Result
Appearance	White powder	Conforms
Identification	Infrared Spectroscopy(IR)/UV Spectroscopy(UV) Matches reference standard	Conforms
Assay	98.0%~102.0%	99.94%
Loss on drying	≤0.5%	0.24%
Residue on ignition	≤0.1%	0.05%
Heavy metals	≤20ppm	Conforms
Individual impurity	≤2.0%	1.15%
Total impurities	≤5.0%	2.07%
Microbial Limit	≤1000cfu/g	+183°
	≤100cfu/g	6.7
	Absence of Escherichia coli, Salmonella spp., and Staphylococcus aureus	Not detected
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: 方臻

