



Certificate of Analysis-Erlotinib

CAS: 183321-74-6

Batch Number: *FTF0250904* Batch Quantity: 35kg

Manufacture Date: Sep.02th,2025 Analysis Date: Sep.03th,2025 Certificate Date: Sep.04th,2025

Storage Store in cool & dry place. Store in well-closed containers.

Shelf life 3 years when properly stored.

ITEM	SPECIFICATION	RESULTS
Appearance	White to off-white, crystalline powder	Complies
Identification (HPLC)	Conforms to Reference Standard	Complies
Assay (by HPLC)	98.5% - 101.5% (on anhydrous basis)	99.8%
Related Substances	Individual impurity≤ 0.50%	0.05%
	Total Impurities≤2.0%	0.15%
Water (Karl Fischer)	< 1.0%	0.4%
Residue on Ignition	< 0.1%	0.05%
Heavy Metals	< 20 ppm	< 10 ppm
Chromatographic Purity	Main peak area ≥ 99.0% of total peak area.	99.78%
Sulfated Ash	< 0.1%	0.04%
Microbial Limits	Total Plate Count <1000cfu/g	<100cfu/g
	Yeast & Moulds <100cfu/g	<10cfuv/g
	E.Coli Negative	Negative
	Salmonella Negative	Negative

Conclusion: Conform with enterprise specification .

QC MANAGER: 刘娟 INSPECTOR: 黄子烨

