



Certificate of Analysis

Product name	Osimertinib mesylate	Manufacture date	Jan.02.2024
Batch number	SW240102	Analysis date	Jan.03.2024
Batch quantity	10kg	Expiry date	Jan.02.2026

ANALYSIS	SPECIFICATION	RUSULT
Appearance	White to off white powder	Conforms
Identification	By IR By HPLC	Conforms Conforms
Solubility	Soluble in dimethylsufoxide, slightly soluble in ethanol and acetonitrile, with Ph dependent aqueous solubility	Conforms
Water content(KF)	≤1.00%	0.38%
Rsidue on ignition	≤0.10%	0.05%
Heavy metals	≤20.00ppm	Conforms
Solvent residue	Acetonitrile≤410ppm Acetone≤5000ppm Tetrahydrofuran:≤720ppm	Not detected 2500ppm Not detected
Related substances	Maximum single impurity: ≤0.20% Total impurities: ≤1.00%	0.05% 0.08%
Assay (HPLC basis on drying)	98.00%~102.00%	99.81%
Conclusion	Conform with specification	

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

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Corrector: 佟丽华

Analyst: 方琼

