

CERTIFICATE OF ANALYSIS

Product Name:	Anastrozole		
Batch No.	202404001	Manufacturing Date	April 7, 2024
Test Date	April 11, 2024	Expiry Date	April 6, 2026
Analytical Results			
Items	Specifications		Results
Description	White crystalline powder		Conforms
Solubility	Very soluble in acetonitrile; Freely soluble in methanol, in acetone, in alcohol, and in tetrahydrofuran.		Conforms
Identification	IR		Conform with standard IR
	HPLC		Conforms
Water	NMT 0.3%		0.1%
Residue on ignition	NMT 0.1%		Conforms
Heavy metals	NMT 0.001%		<10ppm
Related substances	Related Compound B: NMT 0.2%		ND
	Related Compound C: NMT 0.2%		ND
	Related Compound D: NMT 0.1%		ND
	Related Compound E: NMT 0.1%		ND
	Individual unspecified impurity: NMT 0.1%		0.03%
	Total unspecified impurity: NMT 0.2%		0.08%
	Total impurities: NMT 0.5%		0.08%
Residual solvents	Dichloromethane: NMT 0.06%		ND
	Chloroform: NMT 0.006%		ND
	Ethanol: NMT 0.5%		0.04%
	Cyclohexane: NMT 0.08%		0.02%
	Ethylacetate: NMT 0.5%		0.1%
Assay (on dry basis)	98.0% ~ 102.0%		99.8%
Storage	Cool and dry		
Shelf Life	24 months		
Conclusion	The results conform to the USP40.		

Inspector: Carlifor Wu

Verifier: Jack He

