

Certificate of Analysis

Nizatidine

CAS No	76963-41-2	Code	BIOJNIZ001
Batch No	250701	Manufacture Date	Jul.12, 2025
Expiry date	Jul.11, 2027	Quantity	1Kg

Testing Items	Specifications	Results
Appearance	White to almost white crystalline powder	Conform
Identification	Spectrum is accordance with the spectrum obtained with the RS.	Conform
	The retention time of the major peak of the test solution corresponds to that of the reference solution.	Conform
Related substances (HPLC)	Impurity A \leq 0.3%	0.04%
	Impurity C \leq 0.3%	0.02%
	Impurity G \leq 0.3%	0.13%
	Maximum single unknown impurity \leq 0.1%	0.03%
	Total impurities $<$ 1.5%	0.30%
Loss on drying	\leq 1.0%	0.02%
Residue on ignition	\leq 0.1%	0.04%
Heavy metals	\leq 10ppm	Conform
Assay	98.0%~101.0% (Calculated on the dried basis)	100.1%
Conclusion	This product conforms to USP standard	

***Storage condition: Store below 25°C, Protect from moisture and light.**