

Certificate of Analysis

Ketoconazole

CAS No.	65277-42-1	Code	BIOJK1149
Batch No.	DC-011H-2508001	Manufacture Date	Jul.29, 2025
Retest Date	Jul.28, 2029	Quantity	6.5Kgs

Testing Items	Specifications	Results	
Appearance	White or almost white crystalline powder	Complies	
Identification	IR test	Complies	
	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	Complies	
Specific rotation	-1°~+1° (20°C)	0°	
Loss on drying	≤0.5%	0.08%	
Residue on ignition	≤0.1%	0.04%	
Related substances	Individual impurity≤0.10% Total impurities≤2.0%	0.07% 0.18%	
Residual solvents	Methanol $\leq 0.3\%$ Ethanol $\leq 0.5\%$ Ethyl acetate $\leq 0.5\%$ Toluene $\leq 0.089\%$	Not detected <loq(loq=0.005%) 0.10% Not detected</loq(loq=0.005%) 	
Assay	98.0%~102.0% (on dried basis)	100.0%	
Conclusion	This product conforms to USP43 standard		

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

