

402A, 4th floor, building 2, Shenzhen biological incubation base, No. 10, Gaoxin Zhongyi Road, Maling community, Yuehai Street, Nanshan District, Shenzhen

Certificate of Analysis

Product Name	Nilotinib monohydrate	Manufacture Date	2020-10-26
Batch No.	20201026	Report Date	2020-10-27
Batch Quantity	30kg	Retest Date	2022-10-25
CAS No.	923288-90-8	Standard	In-house

Items	Specifications	Results	
Appearance	White to off-white powder	Off-white powder	
Identification	HPLC	Conforms	
	NMR	Conforms	
Water content (KF)	3.0%~4.5%	3.45%	
Residual on ignition	≤0.1%	0.08%	
Residual solvents	Methyl alcohol≤0.3%	N.D.	
	Ethyl alcohol≤0.5%	N.D.	
Related substances	Largest single impurity≤0.1%	0.03%	
	Total impurities≤0.5%	0.08%	
Heavy metal	≤20ppm	Conforms	
Chloride content	5.5%~6.5%	Conforms	
Assay	98.0%~102.0%	99.92%	
Conclusion	The product conforms to the In-house standard.		
Storage condition	Preserve in tight containers, protected from light.		

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