



Certificate of analysis

Product name: Nilotinib hydrochloride monohydrate

Cas number: 923288-90-8

Molecular Formula: $C_{28}H_{22}F_3N_7O \cdot HCl \cdot H_2O$

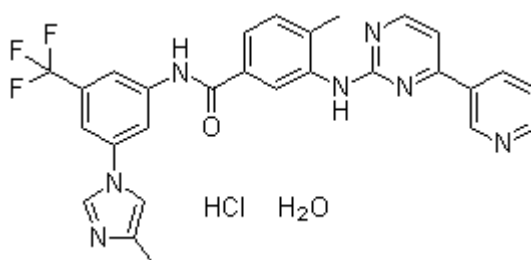
Molecular Weight: 583.99

Date of production: May. 10, 2018

Batch NO: 20180510

Exp Date: May. 09, 2020

Chemical structure:



Items	Specifications	Results
Appearance	Yellowish to off-white crystalline powder	Conforms
Identification	IR UV HPLC	Conforms
Loss on Drying	≤0.5%	0.25%
Sulphated ash	≤0.1%	0.05%
Water	≤5.0%	3.2%
Residual organic solvents	Methanol ≤ 0.3 %; Diethyl ether ≤ 0.5 %; Acetone ≤ 0.5 %; Toluene ≤ 0.089 %; N,N-dimethylformamide ≤ 0.088 %.	Conforms
Heavy Metal	≤ 20ppm	<20ppm
Related Substance	Individual Impurity: ≤0.5% Total Impurities: ≤ 1.0%	0.28% 0.8%
Assay(HPLC)	≥99.0%	99.2%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F