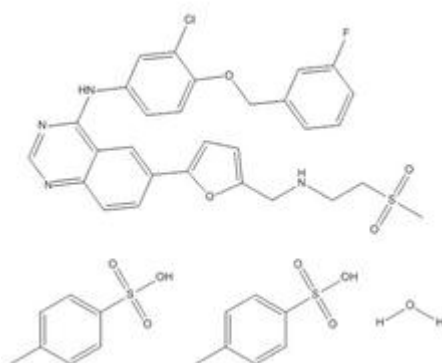


Certificate of Analysis

Lapatinib ditosylate



Batch No: 20180111	Quantity: 35kg	
Manufacture Date: Jan,11,2018	CAS 388082-78-8	
Expiration date : Jan,10. 2020		
Items	Specifications	Results
Appearance	Yellow crystal powder	Yellow crystal powder
H-NMR	Conform with standard	Conform
Water (%)	1.7-2.5%	1.74%

Residue on ignition	≤ 0.5	0.04%
Related substances	Impurity 1 $\leq 0.1\%$	< 0.01%
	Impurity 2 $\leq 0.1\%$	0.02%
	Impurity 3 $\leq 0.1\%$	ND
	Impurity 4 $\leq 0.1\%$	ND
	Impurity 5 $\leq 0.1\%$	0.01%
	Impurity 6 $\leq 0.1\%$	ND
	Impurity 7 $\leq 0.1\%$	< 0.01%
	Impurity 8 $\leq 0.1\%$	0.01%
	Impurity 9 $\leq 0.1\%$	0.04%
	Impurity 10 $\leq 0.1\%$	0.01%
	Impurity 11 $\leq 0.1\%$	ND
	Impurity 12 $\leq 0.1\%$	0.10%
	Impurity 13 $\leq 3\text{ppm}$	ND
	Impurity 14 $\leq 0.1\%$	< 0.01%
	Impurity 15 $\leq 0.1\%$	0.05%
Pd	$\leq 10\text{ppm}$	0.3ppm
Residual Solvents	Methanol $\leq 0.3\%$	ND
	Ethanol $\leq 0.5\%$	ND
	Ethyl acetate $\leq 0.072\%$	ND
	Furanidine $\leq 0.088\%$	ND
	N,N-dimethylformamide $\leq 0.1\%$	ND
	DIPEA $\leq 0.1\%$	0.0082%
Related Impurity by HPLC	Total impurity $\leq 1.0\%$	0.22%
	Single impurity $\leq 0.1\%$	0.06%
Purity (HPLC)	$\geq 99.0\%$	99.78%

Conclusion: the above substance has been tested according to In house Standards , and it meets requirements .