

CERTIFICATE OF ANALYSIS

GEFITINIB

TETS	STANDARD	RESULTS
Appearance	White or almost white powder crystalline powder	White powder
HPLC assay	98.5%—101.5%	99.3%
Loss of drying	≤1.0%	0.76%
Related impurities	Single impurity≤0.5% Total impurity≤1.0%	Single impurity 0.2% Total impurity 0.65%
Heavy metals	Not more than 0.001%	Conforms
Residue on ignition	Not more than 0.2%	0.08%
	NMR:Spectrum of sample corresponds to that of RS	Conforms
Identifications	HPLC:Retention time of sample corresponds to that of RS	Conforms