

## **PRODUCT: IMATINIB MESYLATE**

ITEMS	SPECIFICATIONS
APPEARANCE	White to off-white crystalline or pale yellow powder
SOLUBILITY	Soluble in water and methanol
IDENTIFICATION  a) IR b) HPLC  c) Chemical identification	Conforms to reference spectrum The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution Positive reaction
MELTING POINT	224.0°C ~ 229.0°C
RELATED SUBSTANCES (HPLC)  > Any single impurities  > Total impurities	≤0.10% ≤0.50%
LOSS ON DRYING	≤0.5%
RESIDUE ON IGNITION	≤0.10%
HEAVY METALS	≤20 ppm
RESIDUAL SOLVENTS  a) Ethanol b) Acetone c) Methanol d) Pyridine	≤5000 ppm ≤5000 ppm ≤3000 ppm ≤200 ppm
ASSAY OF METHANESULFONIC ACID	15.0% ~ 17.0%
ASSAY (HPLC) (on dry substance)	98.0% ~ 102.0%