

BTP PHARMACEUTICAL CO., LIMITED

Certificate Of Analysis

Product: : Metronidazole BP2007
Batch No. : 20100526
Batch quantity: 1000kgs
Mfg. date : MAY 07,2010
Expiry date : MAY 07,2014

TESTS	STANDARDS	RESULTS
Appearance	A white or yellowish crystalline powder	Comply
Solubility	slightly soluble in water, in acetone, in alcohol and in methylene, chloride	Comply
Identification	a) Melting point 159-163 °C b) Specific absorbance 365-395 c) Infrared	a) 160.3-160.8 °C b) 375
Loss on drying	0.5% MAX	0.21%
Residue on ignition	0.1% MAX	0.05%
Heavy metals	20PPM MAX	<20PPM
Particle size	40-60 MESH	Comply
Residual solvents	Ethanol \leq 620ppm	\leq 620ppm
Appearance of solution	Suspension II and solution GY6	Comply
Related substances		
1) Impurity	0.1% MAX	0.054%
2) Total impurity	0.2% MAX	0.091%
3) disregard limited	0.01% MAX	Pass
Assay	99.0%-101.0% C ₆ H ₉ N ₃ O ₃	99.53% C ₆ H ₉ N ₃ O ₃

Conclusion : Conform to BP2007