

PRODUCT: ITRACONAZOLE

ITEMS	SPECIFICATIONS
DESCRIPTION	White or almost white powder
SOLUBILITY	Practically insoluble in water, freely soluble in methylene chloride, very slightly soluble in ethanol (96%)
IDENTIFICATION BY IR	To be concordant with Itraconazole working standard
OPTICAL ROTATION (100 mg per ml in methylene chloride)	-0.10° ~+0.10°
LOSS ON DRYING (At 105°C for 4 hours)	NMT 0.5% w/w
RELATED SUBSTANCES BY HPLC <ul style="list-style-type: none"> ➤ 4-Methoxy derivat ➤ 4-Trizolyl isomer ➤ Propyl analog & isopropyl analogue ➤ Epimer ➤ N-Butyl isomer ➤ Didioxolanyl analog ➤ Any other impurity ➤ Total impurities 	NMT 0.5% NMT 0.5% NMT 0.5% NMT 0.5% NMT 0.5% NMT 0.5% NMT 0.1% NMT 1.25%
RESIDUE ON IGNITION	NMT 0.1% w/w
ASSAY (on dry basis)	98.5% w/w ~ 101.5% w/w
RESIDUAL SOLVENTS BY GC-HS <ul style="list-style-type: none"> a) Methanol b) Ethanol c) Methylene chloride d) Chloroform e) Toluene f) Dimethylformamide 	NMT 3000 ppm NMT 5000 ppm NMT 600 ppm NMT 60 ppm NMT 890 ppm NMT 880 ppm