

PRODUCT: QUETIAPINE FUMARATE

ITEMS	SPECIFICATIONS
DESCRIPTION	A white to off white crystalline powder
SOLUBILITY	Soluble in dimethyl formamide, slightly soluble in methanol
IDENTIFICATION=> IR	The infra red absorption spectrum of the sample should exhibit maxima only at the same wavelengths as that of a similar preparation of Quetiapine Fumarate working standard
WATER BY KF	NMT 0.5% w/w
MELTING RANGE	172°C ~ 177°C
RESIDUE ON IGNITION	NMT 0.1% w/w
HEAVY METALS	NMT 10 ppm
RELATED SUBSTANCES BY HPLC <ul style="list-style-type: none"> ➤ 11-Piperazinyl Dibenzo[b.f][1.4]Thiazepine hydrochloride ➤ Des ethanol impurity ➤ Dimer impurity ➤ Max. single unknown impurity ➤ Total impurities 	 NMT 0.20% NMT 0.20% NMT 0.20% NMT 0.10% NMT 1.0%
ASSAY (on anhydrous basis)	98% w/w ~ 102% w/w
FUMARIC ACID CONTENT (By potentiometry)	12.8% w/w ~ 13.5% w/w