

PRODUCT: CELECOXIB

ITEMS	SPECIFICATIONS
DESCRIPTION	A white to off white crystalline powder
SOLUBILITY	Soluble in methanol
IDENTIFICATION a) IR Spectrum b) HPLC	Sample spectra should be concordant with Infrared Absorption spectrum of working standard The retention time of the major peak of the sample solution corresponds to that of standard solution, as obtained in the assay
HEAVY METALS	NMT 20 ppm
RESIDUE ON IGNITION	NMT 0.2%
WATER	NMT 0.50%
ORGANIC IMPURITY (HPLC) a) Celecoxib related compound A b) Celecoxib related compound B c) Individual unspecified Impurity d) Total impurities	NMT 0.40% NMT 0.10% NMT 0.10% NMT 0.50%
ASSAY BY HPLC (on dried basis)	98.0% ~ 102.0%
RESIDUAL SOLVENT ➤ Methanol ➤ Toluene ➤ Benzene	NMT 3000 ppm NMT 890 ppm NMT 1 ppm