

PRODUCT: SERTRALINE HYDROCHLORIDE

ITEMS	SPECIFICATIONS
DESCRIPTION	A white crystalline powder
SOLUBILITY	Moderately soluble in ethanol, slightly soluble in water and in isopropyl alcohol
IDENTIFICATION a) IR Spectrum b) HPLC c) Test for chloride	<p>The infrared spectrum of sample is concordant with that of similarly recorded spectrum of sertraline hydrochloride working standard</p> <p>The retention time of major peak of the sample solution corresponds to that of sertraline hydrochloride from the system suitability solution as obtained in the test for limit of (R,R) sertraline hydrochloride</p> <p>Meets the requirements</p>
RESIDUE ON IGNITION	NMT 0.3%
HEAVY METALS	NMT 30 ppm
WATER CONTENT	NMT 0.50%
LIMIT-OF (R,R) SERTRALINE HYDROCHLORIDE	NMT 1.5% of (R,R) sertraline hydrochloride
ASSAY (By HPLC)	97.0% ~ 102.0% (on the anhydrous basis)