PRODUCT: LEVETIRACETAM

ITEMS	SPECIFICATIONS
DESCRIPTION	White or almost white powder
IDENTIFICATION **a) By IR** **b) By Chiral HPLC (Enantiomeric purity)**	Should conform to standard The retention time of the major peak should correspond to the retention time of S (-) Levetiracetam peak obtained in the chromatogram of system suitability solution
SOLUBILITY	Very soluble in water, soluble in acetonitrile and practically insoluble in hexane
WATER CONTENT BY KF (Use 500 mg sample in methanol as medium)	NMT 0.50% w/w
HEAVY METALS **(Use 2.0g sample in 20 ml of water; 10 ml of 1 ppm lead standard solution; EP method –A)**	Less than 10 ppm
SULPHATED ASH (Use 1.0g of sample)	NMT 0.10% w/w
APPEARANCE OF SOLUTION **(Dissolve 2.0 g of sample in 10 ml of water)**	The solution should be clear and not more intensely coloured than reference solution BY_6
RESIDUAL SOLVENTS **a) Dichloromethane** **b) Ethyl acetate** **(By headspace GC)**	NMT 600 ppm NMT 5000 ppm

ENANTIOMERIC PURITY **Pharmaeuropa impurity D** **[(+)-Levetiracetam]** **(By HPLC, percentage area normalization)**	NMT 0.80
RELATED SUBSTANCES -Test 1 (By HPLC) ➢ **2-Aminobutyric acid** ➢ **USP Levetiracetam related compound B**	 NMT 0.05% w/w NMT 0.10% w/w
RELATED SUBSTANCES-Test 2 (By HPLC) ➢ **Pharmaeuropa impurity A** ➢ **USP Levetiracetam related compound A** ➢ **Pharmaeuropa impurity C** ➢ **Highest unknown impurity** ➢ **Total unknown impurities** ➢ **Total impurities (Sum of related substance Test 1 and Test 2 excluding Pharmaeuropa impurity C)**	 NMT 0.30% w/w NMT 0.05% w/w NMT 0.025% w/w NMT 0.05% w/w NMT 0.10% w/w NMT 0.40% w/w
ASSAY BY HPLC **($C_8H_{14}N_2O_2$, on anhydrous basis)**	98.0% w/w ~ 102.0% w/w