

	<u>PRODUCT:- PREGABALINE</u>	
SR.N O.	TEST	SPECIFICATION
1	Appearance	A White colour Crystalline powder.
2	Solubility	Freely Soluble in Diluted hydrochloric acid and sparingly soluble in water.
3	Identification by FTIR	Shall Comply
4	Specific Optical Rotation	10° to +12°
5	Heavy metals	Maximum 20 ppm
6	Sulphated Ash	NMT 0.1 %
7	Loss on drying	NMT 0.5%
8	Assay (By HPLC)	98.0% to 102%
9	Enantiomeric Purity by HPLC	NMT 0.5%
10	Related substance by HPLC	
	a)Lactum Impurity	NMT 0.5%
	b)The area of any Secondary Peak	NMT 0.5%
	c)The area oa all secondary Peak	NMT 1.0%