

Certificate of Analysis

Product Name	Pregabalin	Manufacture Date	20220819
Batch Number	YG20220822	Analysis Date	20220822
Quantity	300KGS	Expiry Date	20240818

ITEMS		SPECIFICATION	RESULTS
Assay		98.0%~102.0% (calculated on the anhydrous	100.01%
Appearance		White or almost white powder	Conforms
Solubility		Sparingly soluble in water; very slightly soluble in acetonitrile and in methanol, practically insoluble in heptane	Conforms
Identification	A.IR	IR spectrum is accordant with that of reference	Conforms
	B.HPLC	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution, in the Enantiomeric purity	Conforms
Water		Not more than 0.5%	0.15%
Sulfated ash		Not more than 0.1%	0.05%
Related substances	Impurity A	N.M.T.0.15%	0.09%
	Impurity C	N.M.T.0.10%	Not detected
	Impurity D	N.M.T.0.10%	Not detected
	Unspecified Impurity	N.M.T.0.10%	0.02%
	Total Impurities	N.M.T.0.50%	0.11%
Enantiomeric purity		Impurity B N.M.T.0.15%	Not detected
Residual solvents	Ethanol	N.M.T.5000ppm	Not detected
	2-Propanol	N.M.T.5000ppm	455ppm
	Tert-Butylmethyl ether	N.M.T.5000ppm	Not detected
	Ethyl acetate	N.M.T.5000ppm	Not detected
	Tetrahydrofuran	N.M.T.720ppm	Not detected
	Toluene	N.M.T.890ppm	Not detected