

Certificate of Analysis

Product Name		:	Pregabalin IP	Batch Quantity	:	327.00 Kg
Batch No.		:	PEZN240074	Mfg. Date	:	July-2024
Page No.		:	1 of 1	Expiry Date	:	June-2029
Sr. No.		Tests		Standards		Results
						White
1	Description		A White to off white Crystalline powder			Crystalline powder
2	Solubility		Sparingly soluble in water			Complies
	Identification:					
			The IR absorption spectrum of test sample should be concordant with that of spectrum obtained with working standard of pregabalin			Complies
	By IR		The principal peak in the chromatogram			
	ByHPLC		obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a) in assay test .			Complies
4	Enantiomeric purity byH PLC Impurity B		NMT0.15%			0.06%
5	Related substance by HPLC					
	A) Polar impurities eluting before pregabalin					
	Any other secondruy impurity		Not more than0 .1 %			0.08%
	B) Non-polar impurities eluting after pre abalin					
	Impurity A		Not more than 0.15%			0.06%
	Impurity D		Not more than 0.15%			ND
	Any other secondruy impurity		Not more than 0.1%			0.05%
	Total impurities of both methods A & B		Not more than0 .5 %			0.22%
6	Heavy Metals		Not more than 20 oom			Complies
7	Sulphated ash		Not more than 0.1%			0.04%
8	Loss on drying		Not more than0 .5 %			0.21%
9	Assay by HPLC (On Dried Basis)		NLT9 8.0 % and NMT 102 .0%			99.68%