

CERTIFICATE OF ANALYSIS

Product Name	Pregabalin	Specification	Company Standard
CAS No.	148553-50-8	Manufacture Date	2024.9.22
Quantity	500KG	Analysis Date	2024.9.29
Batch No.	BF-240922	Expiry Date	2026.9.21

Items	Specifications	Results
Appearance	Off-white to white crystal powder	White powder
Identification	The infrared absorption spectrum of the sample should concordant with that of the spectrum of working standard of product	Complies
Solubility	Sparingly soluble in water	Complies
Specific Optical Rotation (on anhydrous basis)	+10.0° ~ +12.0°	+10.0°
Loss on Drying (w/w)	≤ 0.50%	0.32%
Sulphate Ash	≤ 0.10%	0.05%
Heavy Metals	≤ 20 ppm	Complies
Enantiomeric Purity	S-The area of peak due to R-Pregabalin is not more than 0.5% the area of the S- Pregabalin.	Complies
Purity by HPLC	Lactam impurities ≤ 0.5%	Not Detected
	Individual impurities ≤ 0.5%	0.437%
	Total impurities ≤ 1.0 %	0.40%
	Purity ≥ 99%	99.60%
Assay	98.0% ~ 102.0% It content not less than 98.0% and not more than 102.0% on dried basis.	99.95%
Package	25kg/drum.	
Storage	Store in a cool and dry place, keep away from strong light and heat.	
Shelf Life	Two years when properly stored.	
Conclusion	The results conforms to the USP38 standard	

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