



CERTIFICATE OF ANALYSIS (COA)

Product name	Pregabalin	Batch No.	AAS-20221201
CAS No.	148553-50-8	Specification	UPS38
Quantity	1652.18kg	Mfg. Date	2022.12.01
Date of Analysis	2022.12.05	Expiry Date	2025.11.30

Test Items	Specification	Test Results
Appearance	Off-white to white powder	White powder
Identification	The infrared absorption spectrum of the sample should concordant with that of the spectrum of working standard of product	Conforms
Solubility	Sparingly soluble in water	Conforms
Specific Rotation On anhydrous basis) (°)	+10.0° to +12.0°	+11.19°
Loss ondrying(w/w)	≤0.5%	0.42%
Sulphate ash	≤0.1%	0.062%
Heavy Metals(%)	≤20ppm	Conforms
Enantiomeric purity	The area ofpeak due to R-Pregabalin is not more than 0.5 % the area of the S-Pregabalin	Conforms
Related substances (HPLC)	Lactam impurities ≤0.5%	0.227%
	Individual impurities ≤0.5%	0.845%
	Total impurities ≤1.0%	99.46%
Assay by HPLC	97.0%~103.0%	99.46%
Conclusion	The test product complies with the requirements of specification.	

Analyst: 李胜男	Checker: 董华	Q. C. Director: 吴云
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