



API CMO & CDMO Manufacturer

CERTIFICATE OF ANALYSIS

Product Name	Pregabalin	Batch No.	Aea20240220PB
CAS No.	148553-50-8	Specification	In-house
Quantity	1268.78kg	Report Date	2024.02.26
MFG. Date	2024.02.20	Expiry Date	2027.02.20

Testing Items	Specifications	Results
Apperance	Off-white to white powder	White powder
Solubility	Sparingly soluble in water	Conforms
Identification	The infrared absorption spectrum of the sample should concordant with that of the spectrum of working standard of product	Conforms
Assay by HPLC	97.0%~103.0%	99.46%
Specific Optical Rotation On anhydrous	+10.0° to +12.0°	+11.19°
Loss on drying (w/w)	≤0.5%	0.42%
Sulphate ash	≤0.1%	0.062%
Heavy Metals(%)	≤20ppm	Conforms
Ash%	MAX.1.0%	0.52%
Heavy Metals	MAX.0.002%	Complies
Enantiomeric purity	The area of peak due to R-Pregabalin is not more than 0.5 % the area of the S-Pregabalin	Complies
Related substances(HPLC)	Lactam impurities ≤0.5% Individual impurities ≤0.5% Total impurities ≤1.0%	0.227% 0.845% 0.568%
Package	Sealed export grade drum & double of sealed plastic bag.	

Storage	Store in a well-closed container away from moisture and direct Sunlight.
Conclusion	The test product complies with the requirements of specification.

Tested/Date 2024.02.26

Approved by

