



### Certificate of Analysis

<b>Product name</b>	Pregabalin	<b>Manufacture date</b>	Agu.15.2023
<b>Batch number</b>	FQ230815	<b>Analysis date</b>	Agu.17.2023
<b>Batch quantity</b>	300kg	<b>Cas</b>	148553-50-8

Item	Standard	Result
<b>Appearance</b>	White or almost white crystalline powder	White crystalline powder
<b>Specific rotation</b>	+9.0~ +11.5 °	+10.79 °
<b>PH</b>	6.0~8.0	6.77
<b>Loss on drying</b>	≤0.5%	0.02%
<b>Residue on ignition</b>	≤0.1%	0.04%
<b>Heavy metals</b>	≤0.002%	<0.002%
<b>Assay (on dried basis)</b>	≥98.5%	100.8%
<b>R-pregabalin(HPLC)</b>	≤0.5%	0.33%
<b>Related substances</b>	S-(+)-mandel ≤0.1%	0.3%
	Unspecific individual impurity≤0.4%	0.08%
	Total impurities≤1.0%	0.10%
<b>Residual solvents</b>	Isopropylketone≤3000ppm Tetrahydrofuran≤720ppm	585.0ppm ND
<b>Conclusion</b>	Comply with the enterprise standard	

<b>Packing description:</b>	Sealed export grade drum & double of sealed plastic bag
<b>Storage:</b>	Store in a tightly closed container ,in a cool and dry place
<b>Shelf life:</b>	2 years when properly stored

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