COA 质量检验报告

杭州凯莫思生化科技有限公司
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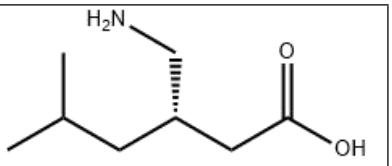
CERTIFICATE OF ANALYSIS

Product Name:		Pregabalin		
Molecular Formula:		C8H17NO2		
Molecular Weigh:		159.23		
Batch No.:		CF20260411001	**CAS No:**	148553-50-8
Mfg. Date:		2026-04-11		
Date of Report:		2026-04-11	**Quantity:**	2500kg
Expired Date:		2029-04-10	**Package:**	Drum
Item		**Specifications**		**Results**
Appearance		White to off-white, crystalline solid		White, crystalline solid
Identification	**IR**	Complies with the test in the test procedure		Complies
	Assay	The retention time of the main peak in sample solution under Assay should be consistent with the retention time of the main peak in standard solution.		Complies
Solubility		Paringly soluble in water and freely soluble in both basic and acidic aqueous solutions.		Complies
Sulphated ash		≤0.10%		0.05%
Loss on drying		≤0.50%		0.06%
Chloride		≤0.10%		<0.10%
Enantiomeric purity		Impurity A: ≤0.15%		0.03%
	Mandelie acid(impurity RRT≈0.66)	≤0.10%		≤0.05%

Related substances	**3-Isobutylpentanedioic acid(impurity RRT≈0.85)**	≤0.15%	≤0.05%
	3-(2- Amino-2-oxoethyl)-5-methylhexanoic acid(impurity RRT≈1.52)	≤0.15%	≤0.05%
	Pregabalin related compound C (impurity RRT≈3.95)	≤0.15%	≤0.05%
	Any unspecified impurity	≤0.10%	≤0.05%
	Total impurities	≤0.80%	≤0.05%
Assay of pregabalin		98.0% ~ 102.0%, calculated on dried substance	98.7%
Residual solvents		2-Propanol: 5000ppm	<50ppm
Storage		Sealed storage at temperature below 25℃	
Conclusion		The test results conforms with USP43 standards