

CERTIFICATE OF ANALYSIS

Product Name	Gabapentin	CAS No.	60142-96-3
Batch No.	GAA-2310016	Test Basis	CMC-SOP-QC-001-03-3-13
Specification	USP	Test Date	October, 2023
Batch Size	1202.2kg	Manufacturing Date	October, 2023
Quantity	1kg	Retest Date	September, 2026
Analytical Results			
Items	Specifications	Results	
Description	White or off-white crystalline powder	White crystalline powder	
Identification	IR: IR spectrum is consistent with Gabapentin RS	Conform	
	HPLC: Conform with the RT of the major peak in HPLC with USP Gabapentin WRS	Conform	
PH	6.5~8.0	7.4	
Water	≤0.5%	0.03%	
Residue on ignition	≤0.1%	0.04%	
Heavy metals	≤0.002%	<0.002%	
Residual solvents	Ethanol: ≤0.50%	0.03%	
Related compounds			
Early eluting impurities	Gabapentin related components A: ≤0.1%	0.005%	
	Gabapentin related components B: ≤0.06%	<LOD(0.02%)	
	Gabapentin related components E: ≤0.10%	<LOD(0.01%)	
	Individual unknown impurity: ≤0.10%	Not detected	
Late eluting impurities	Any individual impurity: ≤0.10%	Not detected	
Total impurities	≤0.5%	0.005%	
Assay	98.0%~102.0%	100.1%	
Conclusion	The batch conforms with USP specifications.		

Inspector: Carlifor Wu

Verifier: Jack He

