



CERTIFICATE OF ANALYSIS

Product Name: GABAPENTIN EP				Product Code: AD 011	
				Mfg. Date	September 2025
Batch No.	BGP2025111			Retest Date	August 2030
Yield(kg)	1073.35			A.R. No.	RGP2025469
Mfg. Lic No. 734				Report Date	06.10.25
S. No.	Test	Met. Ref.	Observation	Limit	
1.	Description	EP	A white crystalline powder.	A White or almost white, crystalline powder.	
2.	Solubility	EP	Sparingly soluble in water, slightly soluble in ethanol (96%), practically insoluble in methylene chloride. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Sparingly soluble in water, slightly soluble in ethanol (96%), practically insoluble in methylene chloride. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	
3.	Polymorphism	EP	It shows polymorphism	It shows polymorphism	
4.	Identification				
4.1	Infrared absorption spectrophotometry	EP	Infrared absorption spectrum of the sample compares with the spectrum obtained with Gabapentin working standard	Infrared absorption spectrum of the sample should compare with the spectrum obtained with Gabapentin working standard.	
5.	Appearance of solution	EP	The solution is clear and colourless.	The solution is clear and colourless	
6.	pH at 25°C (2%w/v solution)	EP	7.1	6.5 to 7.5	
7.	Water	EP	0.1 % w/w	NMT 0.3 % w/w	
8.	Sulphated Ash	EP	0.03 % w/w	NMT 0.1% w/w	
9.	Related Substances:				
9.1	Liquid Chromatography A				
9.1.1	Impurity A	EP	Below disregard limit	NMT 0.15%	
9.1.2	Individual Unknown impurity		Below disregard limit	NMT 0.10%	
9.2	Liquid Chromatography B				
9.2.1	Individual Unknown Impurity	EP	Below disregard limit	NMT 0.05%	
9.3	Total Impurities	EP	0.06 %	NMT 0.5%	

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S. No.	Test	Met. Ref.	Observation	Limit	
10	Assay (On anhydrous basis)	EP	99.6%	97.5 % - 102.0 %	
11	Residual Solvents				
11.1	Acetone	IH	Quantitation limit	NMT 1000 ppm	
11.2	n-Propanol	IH	90 ppm	NMT 1000 ppm	
12.	Chloride	EP	9 ppm	NMT 100 ppm	
Complies with EP & Inhouse Specification and Standards					
Storage: Preserve in well closed containers.					
Signature with Date		Prepared by		Review and Approved by	
		 06.10.25		 06-10-25	
Name		P. ARAVIND KUMAR		K. JEEVANANDHAM	
Designation & Department		Associate Manager - QC		Associate Manager - QA	