



## ANJAN DRUG PRIVATE LIMITED CIN: U24231 TN1990PTC019461

GPD Admin Block, Plot Nos.85-88, 105 - 109, 112 - 116, SIPCOT Export Promotion Industrial Park (EPIP),
Gunraidipoondi -601 201, Tiruvallur District, TamilNadu -India.

Ph. No.: +91-044-23745778, Fax No: +91-044-23748080, EMAIL: info@anjandrug.net, WEBSITE: www.anjandrug.net

$\lceil$				CER	TIFICATE OF ANALYS	IS				
						Product Code		: AD 011		
	Product	Name	:: GABAPENT	Mfg. Date		September 2025				
-	Batch No. BGP2025111				Re		est Date	August 2030		
-	Yield(kg)		1073.35				R. No.	RGP2025469		
	Mfg. Lic No. 734					Rej	port Date	06.10.25		
-	S. No. T		Test	Met. Ref.	Observation			Limit		
1	1.	Description		EP	A white crystalline powder.		A White or almost white, crystalline powder.			
1000 1100	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			
Ī	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.	Appe	arance of	EP	The solution is clear and		The solution colourless	on is clear and		
734400	6.		pH at 25°C EP (2%w/v solution)		7.1		6.5 to 7.5			
	7.	Wate	er	EP	0.1 % w/w		NMT 0.3 % w/w			
	8.	Sulpl	hated Ash	EP 0.03 % w/w			NMT 0.1% w/w			
	9.	Related Substances:								
	9.1	Liquid Chromatography A								
	9.1.1	Impu	ırity A	EP	Below disregard limit		NMT 0.15%			
	9.1.2	Individual Unknown impurity		Er	Below disregard limit		NMT 0.10%			
	9.2	Liquid Chromatography B								
	9.2.1		vidual nown Impurity	EP	Below disregard limit		NMT 0.0	5%		
	9.3		l Impurities	EP 0.06 %			NMT 0.5	%		

## **BULK DRUGS**

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			CF	ERTIFICATE OF ANALYS	SIS		2		
<u></u>				Prod		duct Code	duct Code: AD 011		
Product	Name	: GABAPEN	TIN E			g. Date	September 2025		
Batch No. BGP2025111					Retest Date		August 2030		
Yield(k	g)	1073.35	*****	A.R		R. No.	RGP2025469		
Mfg. Li	c No. 7	734			Report Date		06.10.25		
S. No.		Test Met. Observation			Limit				
10	Assay (On a basis)	nhydrous	EP	99.6%	97.5 % - 1		02.0 %		
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				
Complie	es with	EP & Inhouse	Specific	ration and Standards			**		
		erve in well cl					*		
				Prepared by	Review and Approved by				
S	Signatu	re with Date		8. Valerme 06.10.25		N. 10-25			
	]	Name		P. ARAVIND KUMAF	K. JEEVANANDHAM				
Desig	natio	n & Departm	ent	Associate Manager - QC	Associate Manager - QA				