

Certificate of Analysis

Product name: Gabapentin
Number of analysis: T0009150
Batch number / Weight: 24L12-H10-00425 / 10g
Producer / Producer Batch Number: Zhejiang Chiral Medicine Chemicals Co. Ltd/GAA-2307006
Analysed according to: PH.EUR 11.5

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, crystalline powder	Conform		
Solubility	Sparingly soluble in water, slightly soluble in ethanol, practically insoluble in methylene chloride. It dissolves in dilute acids and dilute solutions of alkali hydroxides	Conform		
Identification	Conform	Conform		IR-spectrum
Appearance of solution	Clear and colourless	Conform		
pH	6,5- 7,5	7,25		2% <i>m/v</i> H ₂ O
Water	<= 0,3	0,05	%	Karl-Fischer
Heavy metals	<= 20	<20	ppm	
Related substances	Conform	Conform		Method A; HPLC
Impurity A	<=0,15	0,005	%	Method A; HPLC
Unspecified impurities	<=0,1	ND	%	Method A; HPLC
Related substances	Conform	Conform		Method B; HPLC
Unspecified impurities	<= 0,05	ND	%	Method B; HPLC
Total impurities	<= 0,5	0,005	%	Method A and Method B
Chlorides	<=100	35	ppm	
Assay Gabapentinum	97,5 - 102,0	100,1	% <i>m/m</i>	
Residual solvents	Conform	Conform		
Ethanol	<=0,50	0,02	%	
Sulfated ash	<=0,1	0,03	%	
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized internal lab.

Release:
 Konstantina Tziolia
 Pharmacist - QA Manager / QP

16/12/2024

Expiration: 06-2026

Conclusion: APPROVED



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