

GABAPENTINA (EUR. PH.)

PRODUCT CODE: 0002443	CAS Nº: 60142-96-3	ANALYSIS Nº: 076/25
MANUFACTURER BATCH: GP/02 2025 0037	CERTIFICATE ID: 45.708	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/02/2025	
METAPH BATCH: 0280325	RETEST DATE: 30/01/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	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	Complies (*)
Identification	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
pH	6.5 - 7.5	6.6
Related substances		
Test A		
Impurity A	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Test B		
Unspecified impurities	=< 0.05 %	< 0.03 %
Total impurities	=< 0.5 %	< 0.03 %
Chlorides	=< 100 ppm	Not Detected
Water	=< 0.3 %	0.05 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	97.5 - 102.0 %	100.3 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

It shows polymorphism.

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Gabapentin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the container tightly closed. Store it in a fresh and dry place.

Analysis date: 10/04/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001542
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