



TECHNICAL DATA SHEET

0002443-TDS-ENG-2023

GABAPENTIN EP		
DESCRIPTION DCI: GABAPENTIN		DESCRIPTION DOE: GABAPENTINA
CAS N°: 60142-96-3	EC N°: 262-076-3	AEMPS CODE: 2641B
MOL. WEIGHT: 171.24	MOL. FORMULA: C ₉ H ₁₇ NO ₂	ARTICLE CODE: 0002443

ATTRIBUTES	SHOULD BE
Appearance	White or almost 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
Identification	Complies
Appearance of solution	Clear and colourless
pH	6.5 - 7.5
Related substances	
Test A	
Impurity A	= < 0.15 %
Unspecified impurities	= < 0.10 %
Test B	
Unspecified impurities	= < 0.05 %
Total impurities	= < 0.5 %
Chlorides	= < 100 ppm
Water	= < 0.3 %
Sulfated ash	= < 0.1 %
Assay	97.5 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

It shows polymorphism (5.9).

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

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.