



TECHNICAL DATA SHEET

0346-TDS-ENG-2024

CARBAMAZEPINA (EUR. PH.)		
DESCRIPTION DCI: carbamazepine		DESCRIPTION DOE: CARBAMAZEPINA
CAS N°: 298-46-4	EC N°: 206-062-7	AEMPS CODE: 561A
MOL. WEIGHT: 236,3	MOL. FORMULA: C ₁₅ H ₁₂ N ₂ O	ARTICLE CODE: 0346

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Very slightly soluble in water, freely soluble in methylene chloride, sparingly soluble in acetone and in ethanol (96 per cent)
Identification A	Complies
Identification B	Complies
Acidity or alkalinity	Complies
Related substances	
Impurity A	=< 0,15 %
Impurity E	=< 0,15 %
Unspecified impurities	=< 0,10 %
Total impurities	=< 0,05 %
Chlorides	< 140 ppm
Loss on drying	=< 0,5 %
Sulfated ash	=< 0,1 %
Assay	98,0 - 102,0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed, in a cool, dry place.

REMARKS

Carbamazepine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.