

TECHNICAL DATA SHEET

M010259-TDS-ENG-2026

VENLAFAXINA HCL (EUR. PH.)		
DESCRIPTION DCI: VENLAFAXINE HYDROCHLORIDE		DESCRIPTION DOE: VENLAFAXINA HIDROCLORURO
CAS Nº: 99300-78-4	EC Nº: 619-421-1	AEMPS CODE: 2664CH
MOL. WEIGHT: 313,86	MOL. FORMULA: C ₁₇ H ₂₈ NO ₂ Cl	ARTICLE CODE: M010259

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Freely soluble in water and in methanol, soluble in anhydrous ethanol, slightly soluble or practically insoluble in acetone
Identification A	Complies
Identification B	Complies
Acidity or alkalinity	=< 0.2 mL of 0.01 M NaOH
Related substances	
Impurity F	=< 0.1 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.2 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 12.3

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

It shows polymorphism.

Venlafaxine Hydrochloride 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.