



TECHNICAL DATA SHEET

002922-TDS-ENG-2023

PSEUDOEFEDRINA HCL (PH.EUR)		
DESCRIPTION DCI: PSEUDOEPHEDRINE HYDROCHLORIDE		DESCRIPTION DOE: PSEUDOEFEDRINA HIDROCLORURO
CAS N°: 345-78-8	EC N°: 206-462-1	AEMPS CODE: 2241CH
MOL. WEIGHT: 201.7	MOL. FORMULA: C10H16ClNO	ARTICLE CODE: 002922

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or colourless crystals
Solubility	Freely soluble in water and in ethanol (96 %), sparingly soluble in methylene chloride
Melting point	about 184 °C
Identification A	Complies
Identification B	Complies
Identification D	Complies
Appearance of solution	Clear and colourless
Acidity or alkalinity	Complies
Specific optical rotation	+61.0 / +62.5
Related substances	
Impurity A	= < 1.0 %
Any other impurity	= < 0.5 %
Sum of impurities other than A	= < 1.0 %
Loss on drying	= < 0.50 %
Sulfated ash	= < 0.10 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Protected from light.

REMARKS

Pseudoephedrine Hydrochloride 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.