



## TECHNICAL DATA SHEET

1499-TDS-ENG-2024

PROMETAZINA HCL (EUR. PH.)		
DESCRIPTION DCI: PROMETHAZINE HYDROCHLORIDE		DESCRIPTION DOE: PROMETAZINA HIDROCLORURO
CAS Nº: 58-33-3	EC Nº: 200-375-2	AEMPS CODE: 49CH
MOL. WEIGHT: 320,89	MOL. FORMULA: C17H21ClN2S	ARTICLE CODE: 1499

ATTRIBUTES	SHOULD BE
Appearance	White or faintly yellowish, crystalline powder
Solubility	Very soluble in water, freely soluble in ethanol (96 %) and in methylene chloride
Melting point	About 222 °C, with decomposition
Identification A	Complies
Identification D	Complies
pH	4.0 - 5.0
Related substances	
Impurity B	=< 0.8 %
Impurity C	=< 0.2 %
Impurity A	=< 0.1 %
Impurity D	=< 0.1 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.2 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

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

### REMARKS

Promethazine 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.