



TECHNICAL DATA SHEET

46433082-TDS-ENG-2024

TRIFLUOPERAZINE HCL (EUR. PH. / BRIT. PH.)		
DESCRIPTION DCI: TRIFLUOPERAZINA DIHIDROCLORURO		DESCRIPTION DOE: ---
CAS Nº: 440-17-5	EC Nº: 207-123-0	AEMPS CODE: 3151DH
MOL. WEIGHT: 480,42	MOL. FORMULA: C ₂₁ H ₂₄ F ₃ N ₃ S	ARTICLE CODE: 46433082

ATTRIBUTES	SHOULD BE
Appearance	A white to pale yellow, crystalline powder
Solubility	Freely soluble in water, soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Identification C	Complies
Identification D	Complies
Identification E	Complies
pH	1,6 - 2,5
Related substances	=< 0,5 %
Loss on drying	=< 1,5 %
Sulfated ash	=< 0,1 %
Assay	99,0 - 101,0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Trifluoperazine 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.