

TRIFLUOPERAZINA HCL (EUR. PH.)

PRODUCT CODE: 46433082	CAS Nº: 440-17-5	ANALYSIS Nº: 158/24
MANUFACTURER BATCH: TH-2402633	CERTIFICATE ID: 42.486	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/02/2024	
METAPH BATCH: 0040624	EXPIRY DATE: 30/01/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	A white to pale yellow, crystalline powder, hygroscopic	A white to pale yellow, crystalline powder, hygroscopic
Solubility	Freely soluble in water, soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Identification D	Complies	Complies
Identification E	Complies	Complies
pH	1.6 - 2.5	1.8
Related substances	=< 0.5 %	< 0.5 %
Loss on drying	=< 1.5 %	0.6 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	99.0 - 101.0 %	99.8 %

COMPLIES WITH

European Pharmacopoeia 11.0

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".

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 20/06/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001497
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