METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

TECHNICAL DATA SHEET

002952-TDS-ENG-2025

PAROXETINA HCL HEMIHIDRATO (EUR. PH.)

DESCRIPTION DCI: PAROXETINE HYDROCHLORIDE HEMIHYDRATE		DESCRIPTION DOE: PAROXETINA HIDROCLORURO HEMIHI
CAS Nº: 110429-35-1	EC Nº: 600-962-7	AEMPS CODE: 2586EV
MOL. WEIGHT: 374,83	MOL. FORMULA: C19H21ClFNO3 1/2·H2O	ARTICLE CODE: 002952

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Slightly soluble in water, freely soluble in methanol, sparingly soluble in ethanol (96 %) and in methylene chloride
Identification A	Complies
Identification B	Complies
Identification C	Complies
Identification D	Complies
Enantiomeric purity	
Impurity D	=< 0.2 %
Related substances	
Impurity A	=< 0.3 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Water	2.2 - 2.7 %
Sulfated ash	=< 0.1 %
Assay	97.5 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep container tightly closed in a well ventilated place.

REMARKS

It shows pseudopolymorphism.

Paroxetine HCl 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.