METAPHARMACEUTICAL IND SL
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PAROXETINA HCL HEMIHIDRATO (EUR. PH.)

PRODUCT CODE: 002952	CAS Nº: 110429-35-1	ANALYSIS Nº: 261/25	
MANUFACTURER BATCH:	5669-25-014	CERTIFICATE ID:	47.852
SUPPLIER BATCH:	----	MANUFACTURING DATE:	10/02/2025
METAPH BATCH:	0040825	EXPIRY DATE:	09/02/2031

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Identification D	Complies	Complies
Enantiomeric purity		
Impurity D	=< 0.2 %	Not Detected
Related substances		
Impurity A	=< 0.3 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Water	2.2 - 2.7 %	2.5 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	97.5 - 102.0 %	99.4 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

It shows pseudopolymorphism.

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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".

All data controlled by Metapharmaceutical Industrial SL.

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

Keep container tightly closed in a well ventilated place.

Analysis date: 25/09/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000772
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