METAPHARMACEUTICAL IND SL
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FLUOXETINA HCL (EUR. PH.)

PRODUCT CODE: 0979	CAS Nº: 56296-78-7	ANALYSIS Nº: 207/25	
MANUFACTURER BATCH:	25FH185	CERTIFICATE ID:	47.309
SUPPLIER BATCH:	----	MANUFACTURING DATE:	30/05/2025
METAPH BATCH:	0030725	EXPIRY DATE:	30/04/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Sparingly soluble in water, freely soluble in methanol, sparingly soluble in methylene chloride	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
pH	4.5 - 6.5	5.1
Optical rotation	-0.05º / +0.05º	+0.00º
Related substances		
Impurity A	=< 0.15 %	Not Detected
Impurity B	=< 0.10 %	Not Detected
Individual impurities	=< 0.10 %	< 0.05 %
Total of impurities	=< 0.5 %	< 0.05 %
Water	=< 0.5 %	0.07 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	98.0 - 102.0 %	98.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

Fluoxetine 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".

Todos los datos controlados por Metapharmaceutical Industrial SL.
(*) Datos adaptados del certificado de análisis del fabricante.

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, well-ventilated area, away from sources of heat, flames, sparks and other sources of ignition.

Analysis date: 07/10/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000478
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