METAPHARMACEUTICAL IND SL
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FLUOXETINA HCL (EUR. PH.)

PRODUCT CODE: 0979	CAS Nº: 56296-78-7	ANALYSIS Nº: 195/22	
MANUFACTURER BATCH:	22FH152	CERTIFICATE ID:	35.795
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/06/2022
METAPH BATCH:	0060922	RETEST DATE:	30/05/2027

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	Complies
pH	4.5 - 6.5	5.5
Optical rotation	-0.05º / +0.05º	0.00º
Related substances		
Impurity A	=< 0.15 %	0.08 %
Impurity B	=< 0.10 %	< 0.05 %
Individual impurities	=< 0.10 %	< 0.05 %
Total of impurities	=< 0.5 %	0.08 %
Water	=< 0.5 %	0.02 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	98.0 - 102.0 %	98.5 %
Residual solvents [In-house]		(*) (**)
Ethyl acetate	=< 5000 ppm	< Lod (0.495 ppm)
Benzene	=< 1 ppm	< Lod (0.050 ppm)
Toluene	=< 100 ppm	< Lod (0.165 ppm)
Particle size		(*)
D (90 %)	< 50 µm	19.0 µm

COMPLIES WITH

European Pharmacopoeia 10.3

REMARKS

Fluoxetine Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

(*) Data adapted from the certificate of analysis of the manufacturer.
(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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: 21/10/2022
Signature: Ferran Gonzalez de Rivera Rier
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000478
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