METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

0979-TDS-ENG-2023

FLUOXETINA HCL (PH.EUR)		
DESCRIPTION DCI: FLUOXETINE HYDROCHLORIDE	DESCRIPTION DOE: FLUOXETINA HIDROCLORURO	
CAS Nº: 56296-78-7	EC Nº: 260-101-2	AEMPS CODE: 2331CH
MOL. WEIGHT: 345.83	MOL. FORMULA: C17H19CIF3NO	ARTICLE CODE: 0979

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Sparingly soluble in water, freely soluble in methanol, sparingly soluble in methylene chloride
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
pH	4.5 - 6.5
Optical rotation	-0.05º / +0.05º
Related substances	
Impurity A	=< 0.15 %
Impurity B	=< 0.10 %
Individual impurities	=< 0.10 %
Total of impurities	=< 0.5 %
Water	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %
Residual solvents [In-house]	
Ethyl acetate	=< 5000 ppm
Benzene	=< 1 ppm
Toluene	=< 100 ppm
Particle size	
D (90 %)	< 50 µm

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

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.

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.

The test for acetonitrile described in the European Pharmacopeia 9.0 monograph is not necessary since this solvent is not

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used in the synthesis (R1-CEP 2003-231-Rev 01).

Properties and uses
Fluoxetine is a selective serotonin reuptake inhibitor (SSRI) derived from phenylpropanolamine. It is easily absorbed in the digestive tract, reaching maximum concentrations at 6 - 8 h. The degree of binding to plasma proteins is 95%. It is widely distributed. It is metabolized in the liver and excreted in the urine. The elimination half-life is long.
It is used orally in the treatment of depression, obsessive-compulsive disorder, bulimia nervosa, and premenstrual dysphoric disorder.

Dosage
Normally at a dose of 20-60 mg / day, depending on the pathology.

Side effects
Gastrointestinal disorders (dry mouth, nausea, vomiting, dyspepsia, constipation, and diarrhea), neurological effects (anxiety, agitation, nervousness, insomnia, drowsiness, fatigue, headache, tremor, dizziness, convulsions, hallucinations, extrapyramidal effects, sexual dysfunction, and serotonin syndrome), and anorexia and weight loss.
Other effects that have been observed are: excessive sweating, pruritus, rashes and urticaria, angioedema, hypersensitivity and anaphylaxis, hyponatremia, hyperprolactinemia and galactorrhea, glycemia alterations, arthralgia and myalgia, and bleeding disorders.

Contraindications
Nursing mothers

Precautions
Elderly, patients with renal or hepatic insufficiency, epilepsy, heart disease, bleeding disorders, diabetes, or treated with ECT. Treatment should be stopped if a rash appears. Do not drive or operate dangerous machinery during treatment. Withdraw the treatment gradually.

Interactions
The most important is with MAOIs and other drugs that act on the mechanisms of neurotransmission by serotonin, since it can trigger a serotonin syndrome. Increases plasma concentrations of benzodiazepines.
Drugs that inhibit cytochrome P450 or related (such as some macrolides) may increase plasma levels of fluoxetine.
Also, by inhibiting said cytochrome, fluoxetine can increase the levels of some antihistamines such as astemizole and terfenadine, increasing the risk of arrhythmias. Protease inhibitors can also increase fluoxetine levels.
Fluoxetine may increase the action of some anticoagulants.
Fluoxetine can lower the convulsive threshold of antiepileptics, antagonizing its action. There is a risk of CNS toxicity when fluoxetine is administered with sumatriptan-type antimagines and sibutramine.

Formulation examples

FLUOXETINE syrup 20 mg/5 mL
FLUOXETINE HCL - **448 mg**
Benzoic acid - **0.1 g**
Flavoring c.s.
Syrup simple c.s.p. - **100 mL**

Modus operandi: Crush and dissolve FLUOXETINE HCL and benzoic acid in the minimum amount of purified water possible. Once dissolved, add the flavoring, and little by little the simple syrup, stirring well. Make up to the final volume with simple syrup. Pack topaz PET bottle.