METAPHARMACEUTICAL IND SL
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# FLUOXETINA HCL (EUR. PH.)

| | | | |
|---|---|---|---|
| PRODUCT CODE: 0979 | CAS Nº: 56296-78-7 | ANALYSIS Nº: 122/24 | |
| MANUFACTURER BATCH: | 24FH074 | CERTIFICATE ID: | 42.105 |
| SUPPLIER BATCH: | ---- | MANUFACTURING DATE: | 01/04/2024 |
| METAPH BATCH: | 0060524 | EXPIRY DATE: | 30/03/2029 |

| 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 % | < 0.05 % |
| Impurity B | =< 0.10 % | < 0.05 % |
| Individual impurities | =< 0.10 % | Not Detected |
| Total of impurities | =< 0.5 % | < 0.05 % |
| Water | =< 0.5 % | 0.2 % |
| Sulfated ash | =< 0.1 % | < 0.1 % |
| Assay | 98.0 - 102.0 % | 99.4 % |

## COMPLIES WITH

European Pharmacopoeia 11.0

## REMARKS

Product fully analysed inside the EU.

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

(*) Data adapted from the manufacturer's certificate of analysis.

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: 07/06/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000478