



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 215778

Product:	FLUOXETINE HYDROCHLORIDE
Lot:	215778
Expiry date:	30/08/2025
Reference:	Cumple PhEur10.5
Synonyms:	
Formule:	C ₁₇ H ₁₉ ClF ₃ NO
Poids moléculaire:	345,83 g/mol

Assay	Result	Specification	
Impurity A	<= 0,25 %	<= 0,25 %	
Impurity C	<= 0,15 %	<= 0,15 %	
Impurity B	<= 0,25 %	<= 0,25 %	
Assay (HPLC)	98,1 %	98,0-102,0%	
Sulphated ashes	0,01 %	<= 0,1%	
Organoleptic properties	Conform		
Total impurities	<= 0,5 %	<= 0,5 %	
Identification	Conform (A,B)		
Unspecified Impurities	<= 0,10 %	<= 0,10 %	
pH of the 1% water solution	5,6	4,5 - 6,5	
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Appearance of solution S	Conform		
Residual solvent: Benzene	<= 2 ppm	<= 2 ppm	#
Optical rotation	0,00	(-0,05) - (+0,05)	
Related substances (HPLC)	Conform		
Residual solvent: Ethyl acetate	<= 5000 ppm	<= 5000 ppm	#
Moisture - K.F.	0,04 %	<= 0,50 %	
Elemental impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white, crystalline powder. Sparingly soluble in water, freely soluble in methanol, sparingly soluble in methylene chloride.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 12/11/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00414 CADILA PHARMACEUTICALS LTD.

Manufacturer batch: 20FH170

Produit	Nom	Capacité	Lot
1370186	FLUOXETINA CLORHIDRATO (FLB) (INACTIVO)	50 g	215778-I-1
1370187	FLUOXETINA CLORHIDRATO (FLB) (INACTIVO)	100 g	215778-J-1
1370188	FLUOXETINA CLORHIDRATO (FLB)	250 g	215778-N-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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