Certificate of Analysis

Product name: **Fluoxetini hydrochloridum**

Batch number / Weight: **21I20-B16-223019 / 5 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **21I20-B16 / INS-22-2325**

Reference Code / No.: **V01462 / A200004**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	White	Conform		
Appearance of solution	Clear / colourless	Conform		
pH	4,5 - 6,5	6,5		
Optical rotation	-0,05 - +0,05	-0,029	°	
Related substances	Conform	Conform		
Impurity A	<=0,15	<0,05		
Impurity B	<=0,10	<0,05		
Unspecified impurities	<=0,10	<0,05		
Total impurities	<=0,3	0,00		
Water (Karl Fischer)	<=0,50	0,023	%	
Sulphated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Fluoxetine hydrochloride	98,0 - 102,0	100,85	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

19-09-2022

Expiration: 31-07-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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