

## Certificate of Analysis

**Product name:** **Fluoxetini hydrochloridum**

**Batch number / Weight:** **21I20-B16-213808 / 5 G**

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

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

Analysis performed by the authorized lab.

Release:  
Agnieszka Pszczółka  
Qualified Person

21-04-2022

Expiration: 31-07-2026

Conclusion: APPROVED

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