

## Certificate of Analysis

**Productname:** Fluoxetini hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-187726B  
**Batchnumber:** 20J29-F02-375378  
**Reference code / No.:** 1122 / A200003  
**Analysed according to:** PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	White	Conform		Chloride
Appearance of solution	Clear / colourless	Conform		2% <i>m/V</i> MeOH 85% <i>V/V</i>
pH	4,5 - 6,5	5,2		1% <i>m/V</i>
Optical rotation	-0,05 - +0,05	0,01	°	2% <i>m/V</i> MeOH 85% <i>V/V</i>
Related substances	Conform	Conform		HPLC
Impurity C	<=0,15	<0,05	%	
Impurity A	<=0,25	n.d.	%	
Impurity B	<=0,25	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Acetonitrile	<=0,1	Conform	%	GC
Water (Karl Fischer)	<=0,5	0,0	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Fluoxetine hydrochloride	98,0 - 102,0	99,5	% <i>m/m</i>	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:  
Paul Hofman  
Pharmacist - Qualified Person

12/16/20

Expiration: 07-2025

Conclusion: APPROVED

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