Fagron

Certificate of Analysis

Productname: **Fluoxetini hydrochloridum**

Number of analysis/Inspection Code: 1 / KEUR-179661B

Batchnumber: **19L09-F03-367157**

Reference code / No.: 1122 / A190002

Analysed according to: **PH.EUR 9.8**

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%m/V MeOH 85%V/V
pH	4,5 - 6,5	5,7		1%m/V
Optical rotation	-0,05 - +0,05	0,00	°	2%m/V MeOH 85%V/V
Related substances	Conform	Conform		HPLC
Impurity C	<=0,15	n.d.	%	
Impurity A	<=0,25	n.d.	%	
Impurity B	<=0,25	n.d.	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Acetonitrile	<=0,1	Conform	%	GC
Water (Karl Fischer)	<=0,5	<0,1	%	
Sulphated ash	<=0,1	<0,1	%	
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	99,4	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

01/15/20

Expiration: 03-2024

Conclusion: APPROVED

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