

Certificate of Analysis

Product name: **Oxitriptanum**

Batch number / Weight: **22A17-B03-221758 / 10 G**

Analysed according to: **Monograph/EP (for Res.Solv.)**

Number of analysis / Inspection Code **22A17-B03 / INS-22-2981**

Reference Code / No.: **V01740 / 21002**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Grey-white or creamy to brown powder, hygroscopic	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Specific optical rotation	-30 - -38	-32		
pH	4,0 - 7,0	5,7		
Related substances	Conform	Conform		
Total impurities	<=0,5	0,29	%	
Arsenic	<= 1,5	Conform	ppm	
Heavy metals	<= 15	<15	ppm	
Water (Karl Fischer)	<=2,0	0,31	%	
Sulphated ash	<= 0,1	0,05	%	
Assay 5-Hydroxytryptophane	98,0 - 101,0	99,7	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<= 1000	76	ppm	
Methyl-t-butylether	<= 100	<2	ppm	

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

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 EL Spol

Release:
Ewelina Gadzinowska
Qualified Person

24-08-2022

Expiration: 10-07-2024

Conclusion: APPROVED

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