

## Certificate of Analysis

**Product name:** **Fenelzine sulfas**

**Batch number / Weight:** **23G26-B03-231769 / 5 G**

**Analysed according to:** **USP**

**Number of analysis / Inspection Code** **23G26-B03 / INS-23-6968**

**Reference Code / No.:** **V01682 / 0000322921**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white to yellowish white powder	Conform		
Appearance	having a characteristic odour			
Identification	acc to USP	Conform		
Identification B	acc to USP	Conform		
Identification C	acc to USP	Conform		
Melting range	164-168	167,0	°C	
pH	1,4-1,9	1,70		
Loss on drying	<=1,0	0,17	%	
Limit of hydrazine	<=0,1	0,01	%	
Ordinary impurities	<=2,0	<2	%	
Assay	98,0-102,0	100,28	%m/m	
Residual solvents	CPMP/ICH/82 260/06	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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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

29-10-2023

Expiration: 05-11-2025

Conclusion: APPROVED

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

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