

## FENELZINA SULFATO USP

PRODUCT CODE: 2230	CAS Nº: 156-51-4	ANALYSIS Nº: 043/25
MANUFACTURER BATCH: 21084064	CERTIFICATE ID: 45.287	
SUPPLIER BATCH: 24I06-G240187	MANUFACTURING DATE: 13/03/2021	
METAPH BATCH: 0170225	EXPIRY DATE: 13/03/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White to off-white crystalline powder	White crystalline powder (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Identification C	Complies	Complies (*)
Assay	98.0 - 102.0 %	99.1 %
Ordinary impurities	Complies	Complies
Limit of hydrazine	=< 0.1 %	0.09 %
Loss on drying	=< 1.0 %	0.6 %
pH	1.4 - 1.9	1.7
Melting point	164 - 168 °C	Complies

### COMPLIES WITH

USP 2025

### REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

PHENELZINE SULFATE is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(\*) Data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

### STORAGE

Store in a cool, dry and well-ventilated place. Protect from direct sunlight.

Analysis date: 04/03/2025  
 Signature: Albert Sánchez López (QP)  
 Conclusion: Complies  
 Original certificate available upon request

Manufacturer: 40000855  
 SIEGFRIED PHARMA CHEMIKALIEN MIDEN GmbH  
 Karlstrasse, 15  
 32423 MIDEN  
 (Alemania)

