

## Certificate of Analysis

**Product name:** Sulpiridum  
**Batch number / Weight:** 23G31-B09-234518 / 100 G  
**Analysed according to:** Ph.Eur.11.2  
**Number of analysis / Inspection Code** 23G31-B09 / INS-23-6278  
**Reference Code / No.:** V01120 / 23010

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / $\leq Y_6$	Conform		
Impurity A	$\leq 0,1$	$< 0,1$	%	
Related substances	Conform	Conform		
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 0,3$	0,00	%	
Chlorides	$\leq 100$	$< 100$	ppm	
Iron	$\leq 10$	$< 10$	ppm	
Loss on drying	$\leq 0,5$	0,12	%	
Sulphated ash	$\leq 0,1$	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Sulpiride	98,5 - 101,0	100,41	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

fagron.pl

Fagron Services Northern Europe Sp. z o.o.  
 ul. Armii Krajowej 3  
 32-540 Trzebinia, Poland  
 e-mail: fsne@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 Fagron PL lab

Release:  
Ewelina Gadzinowska  
Qualified Person

22-12-2023

Expiration: 30-04-2028

Conclusion: APPROVED

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