

## Certificate of Analysis

**Product name:** **Sulpiridum**

**Batch number / Weight:** **22K26-B11-230232 / 30 G**

**Analysed according to:** **Ph.Eur.11.1**

**Number of analysis / Inspection Code** **22K26-B11 / INS-22-10046**

**Reference Code / No.:** **V01120 / 22023**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / $\leq Y6$	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	$\leq 0,1$	0,00	%	
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	100,05	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	$\leq 3000$	$< 3000$	ppm	

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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:  
Dominika Soltysik  
Qualified Person

28-06-2023

Expiration: 31-08-2027

Conclusion: APPROVED

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