

Certificate of Analysis

Product name: **Sulpiridum**
Batch number / Weight: **21K12-B20-216754 / 100 G**
Analysed according to: **Ph. Eur.**

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	$\leq 0,3$	$< 0,05$	%	
Chlorides	≤ 100	< 100	ppm	
Iron	≤ 10	Conform	ppm	
Loss on drying	$\leq 0,5$	0,03	%	
Sulphated ash	$\leq 0,1$	0,03	%	
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	99,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Agnieszka Pszczółka
 Qualified Person

21-02-2022

Expiration: 28-02-2026

Conclusion: APPROVED

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