

Certificate of Analysis

Product name: Sulpiridum

Batch number / Weight: 22K26-B11-230161 / 10 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 / $\leq Y_6$	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	≤ 100	< 100	ppm	
Iron	≤ 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	≤ 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

29-06-2023

Expiration: 31-08-2027

Conclusion: APPROVED

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