

Certificate of Analysis

Productname: Sulpiridum
Number of analysis/Inspection Code: 1 / KEUR-186812B
Batchnumber: 20I16-F01-374538
Reference code / No.: 1188 / 20024
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / <=Y6	Conform		10% <i>m</i> /V dil HAc
Impurity A	<=0,1	Conform	%	TLC
Related substances	Conform	Conform		HPLC
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,3	0,0	%	
Chlorides	<=100	Conform	ppm	
Iron	<=10	Conform	ppm	
Loss on drying	<=0,5	0,0	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Sulpiride	98,5 - 101,0	100,3	% <i>m</i> / <i>m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

11/04/20

Expiration: 07-2025

Conclusion: APPROVED

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