

Certificate of Analysis

Productname: Sulpiridum
Number of analysis/Inspection Code: 1 / KEUR-183021B
Batchnumber: 20C04-F03-370523
Reference code / No.: 1188 / 19038
Analysed according to: PH.EUR10.1

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	0,1	%	TLC
Related substances	Conform	Conform		HPLC
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=0,3	<=0,1	%	
Chlorides	<=100	Conform	ppm	
Iron	<=10	Conform	ppm	
Loss on drying	<=0,5	0,4	%	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	99,4	% <i>m</i> /m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

05/29/20

Expiration: 11-2024

Conclusion: APPROVED

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