

## Certificate of Analysis

**Productname:** Sulpiridum  
**Number of analysis/Inspection Code:** 1 / KEUR-183002B  
**Batchnumber:** 20C04-F03-370522  
**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

05/28/20

Expiration: 11-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.