

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

Appearance(Almost) white, crystalline powderConformIR-spectrumIdentification BConformConformIR-spectrumAppearance of solutionClear / <=Y6Conform10%m/V dil HAcImpurity A<=0,10,1%TLCRelated substancesConformConformWILCHPLCUnspecified impurities<=0,100,05%-Total impurities<=0,3<=0,1%-Chlorides<=100Conformppm-Iron<=10Conform0,04%105°CSulphated ash<=0,10,0%-Metallic residuesCHMP/ICH/353369/2013ConformData producerResidual solventsCHMP/ICH/82260/2006Sim UniverData producerAssav Sulpiride98.5 - 101.099.4%m/mDried	Tests	Requirement	Result	Unit	Standard remark
Identification BConformIR-spectrumAppearance of solutionClear / <=Y6					
Appearance of solutionClear / <=Y6Conform10%m/V dil HAcImpurity A<=0,1	Appearance	(Almost) white, crystalline powder	Conform		
Impurity A<=0,10,1%TLCRelated substancesConformConformHPLCUnspecified impurities<=0,10	Identification B	Conform	Conform		IR-spectrum
Related substancesConformHPLCUnspecified impurities<=0,10	Appearance of solution	Clear / <=Y6	Conform		10%m/V dil HAc
Unspecified impurities<=0,100,05%Total impurities<=0,3	Impurity A	<=0,1	0,1	%	TLC
Total impurities<=0,3<=0,1%Chlorides<=100	Related substances	Conform	Conform		HPLC
Chlorides<=100ConformppmIron<=10	Unspecified impurities	<=0,10	0,05	%	
Iron<=10ConformppmLoss on drying<=0,5	Total impurities	<=0,3	<=0,1	%	
Loss on drying<=0,50,4%105°CSulphated ash<=0,1	Chlorides	<=100	Conform	ppm	
Sulphated ash<=0,10,0%Metallic residuesCHMP/ICH/353369/2013ConformData producerResidual solventsCHMP/ICH/82260/2006ConformData producer	Iron	<=10	Conform	ppm	
Metallic residuesCHMP/ICH/353369/2013ConformData producerResidual solventsCHMP/ICH/82260/2006ConformData producer	Loss on drying	<=0,5	0,4	%	105°C
Residual solvents CHMP/ICH/82260/2006 Conform Data producer	Sulphated ash	<=0,1	0,0	%	
	Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Sulpiride 98.5 - 101.0 99.4 %m/m Dried	Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
	Assay Sulpiride	98,5 - 101,0	99,4	%m/m	Dried
TSE/BSE-statement: No contamination with TSE/BSE-risk materials Conform Data producer	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

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