

Certificate of Analysis

Productname: Methadoni hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-197585B
Batchnumber: 23A25-F01-384689
Reference code / No.: 1370 / 2230H029
Analysed according to: PH.EUR11.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White, crystalline powder	Conform		
Identification A	-0,05 - +0,05	Conform	°	Optical rotation
Identification C	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Chloride
Appearance of solution	Clear and colourless	Conform		5% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Optical rotation	-0,05 - +0,05	0,01	°	5% <i>m/V</i> ; 2 dm
Related substances	Conform	Conform		GC
Impurity A	<=0,1	<0,1	%	
Impurity B	<=0,1	<0,1	%	
Impurity C	<=0,1	<0,1	%	
Impurity D	<=0,1	<0,1	%	
Impurity E	<=0,1	<0,1	%	
Unspecified impurities	<=0,10	<0,10	%	
Total impurities	<=0,3	<0,1	%	
Loss on drying	<= 0,5	0,0	%	105 °C
Sulphated ash	<= 0,1	<=0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Methadone hydrochloride	99,0 - 101,0	100,4	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Synergy Health Utrecht B.V.

Manufacturer / Country : Siegfried Ltd. AG / CH
CEP : Not available

Release:
Anthony Amoureux
Qualified Person

05/24/23

Expiration: 20-07-27

Conclusion: APPROVED

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