Fagron

Certificate of Analysis

Productname:	**Methadoni hydrochloridum**
Number of analysis/Inspection Code:	1 / KEUR-198863B
Batchnumber:	**23G28-F02-386057**
Reference code / No.:	1370 / 2314H055
Analysed according to:	**PH.EUR11.2**

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%m/V
Acidity or alkalinity	Conform	Conform		
Optical rotation	-0,05 - +0,05	0,01	°	5% m/V; 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	0,1	%	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	100,5	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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

Manufacturer / Country   :   Siegfried Ltd. AG / CH
CEP   :

Release:
Anthony Amoureus
Qualified Person

18-04-24

Expiration: 05-04-28

Conclusion: APPROVED

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