

## Certificate of Analysis

**Productname:** **Methadoni hydrochloridum**  
**Number of analysis/Inspection Code:** 1 / KEUR-198847B  
**Batchnumber:** **23G28-F02-386062**  
**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% <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	0,1	%	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	% <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** :

Release:  
Anthony Amoureux  
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.

**pdfMachine**

**A pdf writer that produces quality PDF files with ease!**

Produce quality PDF files in seconds and preserve the integrity of your original documents. Compatible across nearly all Windows platforms, simply open the document you want to convert, click "print", select the "Broadgun pdfMachine printer" and that's it! Get yours now!