

Certificate of Analysis

Productname: **Methadoni hydrochloridum**
Number of analysis/Inspection Code: 1 / KEUR-196228B
Batchnumber: **22E02-F04-382616**
Reference code / No.: 1370 / 2204H029
Analysed according to: **PH.EUR10.8**

| 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 | 0,00 | ° | 5% <i>m/V</i> ; 2 dm |
| Related substances | Conform | Conform | | GC |
| Impurity A | <=0,1 | n.d. | % | |
| Impurity B | <=0,1 | n.d. | % | |
| Impurity C | <=0,1 | n.d. | % | |
| Impurity D | <=0,1 | n.d. | % | |
| Impurity E | <=0,1 | n.d. | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities | <=0,3 | <0,05 | % | |
| Loss on drying | <= 0,5 | 0,0 | % | 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 Methadone hydrochloride | 99,0 - 101,0 | 99,5 | % <i>m/m</i> | Dried |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| CEP | CEP available | Conform | | Data producer |

Analysis performed by the authorized laboratory Proxylabs.

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

Release:
Anthony Amoureux
Qualified Person

11/09/22

Expiration: 10-01-27

Conclusion: APPROVED

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