

## Certificate of Analysis

**Productname:** Cocaini hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-198101B  
**Batchnumber:** 23G14-F02-385188  
**Reference code / No.:** 1242 / 22-00464  
**Analysed according to:** PH.EUR11.2

| Tests                                     | Requirement   | Result  | Unit         | Standard remark         |
|---|---|---------|--------------|-------------------------|
| Appearance                                | (Almost) white, crystalline powder or colourless crystals | Conform |              |                         |
| Identification B                          | Conform   | Conform |              | IR-spectrum             |
| Identification D                          | White   | Conform |              | Chloride                |
| Appearance of solution                    | Clear and colourless                                      | Conform |              | 2% <i>m/V</i>           |
| Acidity                                   | Conform   | Conform |              |                         |
| Specific optical rotation                 | -70 - -73   | -72     |              | 2.5% <i>m/V</i> ; dried |
| Readily carbonisable substances           | Conform   | Conform |              |                         |
| Related substances                        | Conform   | Conform |              | HPLC                    |
| Any impurity eluting after principal peak | <=0,1   | <0,1    | %            |                         |
| Total impurities                          | <=0,5   | <0,1    | %            |                         |
| Loss on drying                            | <=0,5   | 0,1     | %            | 105°C                   |
| Sulphated ash                             |   | Conform | %            |                         |
| Metallic residues                         | CHMP/ICH/353369/2013                                      | Conform |              | Data producer           |
| Residual solvents                         | CHMP/ICH/82260/2006                                       | Conform |              | Data producer           |
| Assay Cocain hydrochloride                | 98,5 - 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** : MacFarlan Smith Ltd. / GB  
**CEP** :

Release:  
Anthony Amoureux  
Qualified Person

09/12/23

Expiration: 31-12-26

Conclusion: APPROVED

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