

**CERTIFICATE OF ANALYSIS**

|                                                                                                                                                                                                             |                                                           |                                       |                                                                                                                          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| Product<br><b>NALTREXONE HYDROCHLORIDE</b>                                                                                                                                                                  |                                                           | Date of manufacture<br><b>03/2015</b> |                                                                                                                          |
| Batch N.<br><b>NT 2/2015</b>                                                                                                                                                                                |                                                           | Net weight                            |                                                                                                                          |
| Analysis record N.<br>22101                                                                                                                                                                                 |                                                           | N. of packages                        | According to Current E.P. and<br>Certificate of suitability R1-CEP 2006-117-Rev 01                                       |
|                                                                                                                                                                                                             | <b>Tests</b>                                              | <b>Results</b>                        | <b>Specification</b>                                                                                                     |
| 1                                                                                                                                                                                                           | Characters                                                |                                       |                                                                                                                          |
|                                                                                                                                                                                                             | Appearance                                                | Complies                              | White or almost white powder,<br>very hygroscopic                                                                        |
|                                                                                                                                                                                                             | Solubility                                                | Complies                              | Freely sol. in water, slightly sol.<br>in ethanol 96 %, practically<br>insol. in methylene chloride                      |
| 2                                                                                                                                                                                                           | Identification                                            |                                       |                                                                                                                          |
|                                                                                                                                                                                                             | A) IR Spectrum (2.2.24)                                   | Complies                              | Complies with standard                                                                                                   |
|                                                                                                                                                                                                             | B) Reaction (a) of chloride (2.3.1)                       | Positive                              | Positive                                                                                                                 |
| 3                                                                                                                                                                                                           | Appearance of solution S<br>(2.2.1)<br>(2.2.2, method II) | Complies<br>Complies                  | Clear<br>≤ Y <sub>6</sub> or B <sub>6</sub>                                                                              |
| 4                                                                                                                                                                                                           | Acidity or alkalinity                                     | 0.10                                  | ≤ 0.2 (HCl or NaOH 0.02 M)                                                                                               |
| 5                                                                                                                                                                                                           | Specific optical rotation (a.s., 2.2.7)                   | -190                                  | Between -195 and -187                                                                                                    |
| 6                                                                                                                                                                                                           | Related substances (HPLC, 2.2.29)                         |                                       |                                                                                                                          |
|                                                                                                                                                                                                             | Impurity A                                                | nd                                    | ≤ 0.1                                                                                                                    |
|                                                                                                                                                                                                             | Impurity B                                                | <0.05                                 | ≤ 0.1                                                                                                                    |
|                                                                                                                                                                                                             | Impurity C                                                | <0.05                                 | ≤ 0.2                                                                                                                    |
|                                                                                                                                                                                                             | Impurity D                                                | <0.05                                 | ≤ 0.2                                                                                                                    |
|                                                                                                                                                                                                             | Impurity E                                                | 0.09                                  | ≤ 0.2                                                                                                                    |
|                                                                                                                                                                                                             | Impurity F                                                | <0.05                                 | ≤ 0.2                                                                                                                    |
|                                                                                                                                                                                                             | Impurity G                                                | <0.05                                 | ≤ 0.2                                                                                                                    |
|                                                                                                                                                                                                             | Impurity H                                                | nd                                    | ≤ 0.1                                                                                                                    |
|                                                                                                                                                                                                             | Impurity I                                                | nd                                    | ≤ 0.1                                                                                                                    |
|                                                                                                                                                                                                             | Impurity J                                                | nd                                    | ≤ 0.1                                                                                                                    |
|                                                                                                                                                                                                             | Any other impurity (unspecified)                          | nd                                    | ≤ 0.1 (each)                                                                                                             |
|                                                                                                                                                                                                             | Unknown impurities                                        | 0.06                                  | ≤ 0.10 (each)                                                                                                            |
|                                                                                                                                                                                                             | Total                                                     | 0.15                                  | ≤ 1.0                                                                                                                    |
| 7                                                                                                                                                                                                           | Residual solvents                                         |                                       |                                                                                                                          |
|                                                                                                                                                                                                             | Ethanol                                                   | 6                                     | ≤ 5000                                                                                                                   |
| 8                                                                                                                                                                                                           | Water (2.5.12)                                            | 9.6                                   | ≤ 10.0                                                                                                                   |
| 9                                                                                                                                                                                                           | Sulphated ash (2.4.14)                                    | 0.06                                  | ≤ 0.1                                                                                                                    |
| 10                                                                                                                                                                                                          | Assay (a.s., 2.2.20)                                      | 99.8                                  | Between 98.0 and 102.0                                                                                                   |
| Notes<br><br>a.s. = anhydrous substance<br>nd = not detected (below detection limit)<br>Disregard limit for HPLC impurities = 0.05 percent (LOQ)<br>Storage: in an airtight container, protected from light |                                                           | Assay date<br><br>28/03/2015          | The head of Q.C. department<br><br><b>S.A.L.A.R.S. S.p.A.</b><br><b>QUALIFIED PERSON</b><br><b>(Dr. Claudio Caraffi)</b> |