

DAL 1932

**S.A.L.A.R.S. S.p.A.**

Sede e luogo di produzione:

Via San Francesco n° 5 - 22100 COMO ITALY

Tel. 0039 031 520610 / 031 524095 Fax 0039 031 520751

Internet : <http://www.salars.it> E-mail : [contact@salars.it](mailto:contact@salars.it)

Lot: 0100911

## CERTIFICATE OF ANALYSIS

|                                                          |                                                     |                                                                                 |                                                                                               |
|----------------------------------------------------------|-----------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Product<br><b>NALTREXONE HYDROCHLORIDE</b>               |                                                     | Date of manufacture<br>04/2011                                                  |                                                                                               |
| Batch N.<br>NT 2/2011                                    |                                                     | Net weight                                                                      |                                                                                               |
| Analysis record N.<br>21268                              |                                                     | Retest date<br>03/2016                                                          |                                                                                               |
| N. of packages                                           |                                                     | According to Current E.P. and Certificate of suitability R0-CEP 2006-117-Rev 00 |                                                                                               |
| 1                                                        | Tests                                               | Results                                                                         | Specifications                                                                                |
| 1                                                        | Characters                                          |                                                                                 |                                                                                               |
|                                                          | Appearance                                          | Complies                                                                        | White or almost white powder, very hygroscopic                                                |
|                                                          | Solubility                                          | Complies                                                                        | Freely sol. in water, slightly sol. in ethanol 96 %, practically 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 (2.2.1) (2.2.2, method II) | Complies<br>Complies                                                            | Clear<br>≤ Y <sub>6</sub> or B <sub>6</sub>                                                   |
| 4                                                        | Acidity or alkalinity                               | 0.08                                                                            | ≤ 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                                          | <0.05                                                                           | ≤ 0.1                                                                                         |
|                                                          | Impurity B                                          | 0.09                                                                            | ≤ 0.1                                                                                         |
|                                                          | Impurity C                                          | <0.05                                                                           | ≤ 0.2                                                                                         |
|                                                          | Impurity D                                          | nd                                                                              | ≤ 0.2                                                                                         |
|                                                          | Impurity E                                          | <0.05                                                                           | ≤ 0.2                                                                                         |
|                                                          | Impurity F                                          | <0.05                                                                           | ≤ 0.2                                                                                         |
|                                                          | Impurity G                                          | <0.05                                                                           | ≤ 0.2                                                                                         |
|                                                          | Impurity H                                          | <0.05                                                                           | ≤ 0.1                                                                                         |
|                                                          | Impurity I                                          | nd                                                                              | ≤ 0.1                                                                                         |
|                                                          | Impurity J                                          | <0.05                                                                           | ≤ 0.1                                                                                         |
|                                                          | Any other impurity (unspecified)                    | nd                                                                              | ≤ 0.1 (each)                                                                                  |
|                                                          | Unknown impurities                                  | 0.09                                                                            | ≤ 0.10 (each)                                                                                 |
|                                                          | Total                                               | 0.24                                                                            | ≤ 1.0                                                                                         |
| 7                                                        | Residual solvents                                   |                                                                                 |                                                                                               |
|                                                          | Ethanol                                             | 8                                                                               | ≤ 5000                                                                                        |
| 8                                                        | Water (2.5.12)                                      | 7.2                                                                             | ≤ 10.0                                                                                        |
| 9                                                        | Sulphated ash (2.4.14)                              | 0.05                                                                            | ≤ 0.1                                                                                         |
| 10                                                       | Assay (a.s., 2.2.20)                                | 100.1                                                                           | Between 98.0 and 102.0                                                                        |
| Notes                                                    |                                                     | Assay date                                                                      | The head of Q.C. department                                                                   |
| a.s. = anhydrous substance                               |                                                     | 03/05/2011                                                                      | <b>S.A.L.A.R.S. S.p.A.</b>                                                                    |
| nd = not detected (under detection limit)                |                                                     |                                                                                 | QUALIFIED PERSON                                                                              |
| Disregard limit for HPLC impurities = 0.05 percent (LOQ) |                                                     |                                                                                 | (Dr. Claudio Caraffi)                                                                         |
| Storage: in an airtight container, protected from light  |                                                     |                                                                                 |                                                                                               |