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# CERTIFICATE OF ANALYSIS

| Product **NALTREXONE HYDROCHLORIDE** | | | Date of manufacture 03/2018 |
|---|---|---|---|
| Batch N. NTP 01/2018 | Retest date 02/2023 | | |
| Analysis record N. 22614 | According to Current E.P. and Certificate of suitability R1-CEP 2006-117-Rev 02 | | |

| | Tests | Results | Specification | Units |
|---|---|---|---|---|
| 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 | |
| 3 | Appearance of solution S | | | |
| | (2.2.1) | Clear | Clear | |
| | (2.2.2, method II) | Complies | ≤ $Y_6$ or $B_6$ | |
| 4 | Acidity or alkalinity | 0.07 | ≤ 0.2 (HCl or NaOH 0.02 M) | ml |
| 5 | Specific optical rotation (a.s., 2.2.7) | -188 | Between -195 and -187 | degrees |
| 6 | Related substances (HPLC, 2.2.29) | | | |
| | Impurity A | nd | ≤ 0.1 | percent |
| | Impurity B | <0.05 | ≤ 0.1 | percent |
| | Impurity C | <0.05 | ≤ 0.2 | percent |
| | Impurity D | <0.05 | ≤ 0.2 | percent |
| | Impurity E | <0.05 | ≤ 0.2 | percent |
| | Impurity F | <0.05 | ≤ 0.2 | percent |
| | Impurity G | <0.05 | ≤ 0.2 | percent |
| | Impurity H | nd | ≤ 0.1 | percent |
| | Impurity I | <0.05 | ≤ 0.1 | percent |
| | Impurity J | <0.05 | ≤ 0.1 | percent |
| | Any other impurity (unspecified) | nd | ≤ 0.1 (each) | percent |
| | Unknown impurities | <0.05 | ≤ 0.10 (each) | percent |
| | Total | <0.05 | ≤ 1.0 | percent |
| 7 | Residual solvents | | | |
| | Ethanol | 5 | ≤ 5000 | ppm |
| 8 | Water (2.5.12) | 1.8 | ≤ 10.0 | percent |
| 9 | Sulfated ash (2.4.14) | 0.06 | ≤ 0.1 | percent |
| 10 | Assay (a.s., 2.2.20) | 100.6 | Between 98.0 and 102.0 | percent |

Notes

a.s. = anhydrous substance
nd = not detected (below detection limit)
Disregard limit for HPLC impurities = 0.05 percent (LOQ)
Storage: in an airtight container, protected from light

Assay date
16/03/2018

The head of Q.C. department
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