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Date: 5.10.20

Cust.No: 96888

**Certificate of analysis**

Report-No.: 112685246 - 99 002  
Batch: 10218  
Article: 83515 Jervine

| Test  | Unit | Limit   | Testresult         |
|---|------|---------|--------------------|
| Appearance, SOP 100005  |      | powder  | Conform            |
| Color, SOP 100006   |      | white   | Conform            |
| Solubility, SOP 105001:<br>Chloroform   |      | soluble | Conform<br>Conform |
| Identification (HPLC-MS/MS), SOP 204120   |      | Conform | Conform            |
| Identification (UV spectrum from HPLC-DAD analysis) according to specification, SOP 204311                    |      | Conform | Conform            |
| Identification (IR-spectroscopy, Ph.Eur. 10.3, 2.2.24)/USP 43 NF 37 <197>), SOP 206000                        |      | Conform | Conform            |
| Identification (1H-NMR-spectroscopy), (outsourced), SOP 206010  |      | Conform | Conform            |
| Identification (13C-NMR-spectroscopy), (outsourced), SOP 206020   |      | Conform | Conform            |
| Water content, (micro determination, coulometric titration), Ph.Eur. 10.0., 2.5.32, SOP 304291:<br>Mean value | %    |         | 2.3                |
| Peakpurity, (HPLC), SOP 401367  |      | Conform | Conform            |

**Certificate of analysis**

Report-No.: 112685243 - 99 002  
 Batch: 10218  
 Article: 83515 Jervine

| Test  | Unit | Limit    | Testresult |
|---|------|----------|------------|
| Jervine (HPLC), method 1 (%AU), SOP 441430                            | %    | >= 95.00 | 99.50      |
| Residual solvents, (headspace-GC), SOP 805765:<br>Residual solvents   | %    |          | 0.24       |
| Inorganic impurities, (ICP-MS), for reference substances, SOP 811701: |      |          |            |
| Sodium  | %    |          | < 0.1      |
| Potassium   | %    |          | < 0.1      |
| Magnesium   | %    |          | < 0.1      |
| Calcium   | %    |          | < 0.1      |
| Aluminium   | %    |          | < 0.1      |
| Phosphorus  | %    |          | < 0.1      |
| Sulfur  | %    |          | < 1.0      |
| Content*, SOP 890000  | %    |          | 97         |

**Assessment:**

The above mentioned reference substance meets the specification.

\*The absolute content is calculated considering the chromatographic purity, and if available, the content of water, residual solvents and inorganic impurities according to the following formula:  
 Content = (100% - water content (%) - residual solvents (%) - inorganic impurities (%)) x chromatographic purity (%) / 100.

The chromatographic purity is checked regularly: the last analysis has been performed in September 2020.

The reference substance cannot be documented with an expiry date. The pack is closed and is recommended to be stored as indicated. The unopened product is guaranteed to fulfill the specifications of this analytical report for a period of 60 months. Once opened we can no longer guarantee the stability of the material.

Vestenbergsreuth, 5.10.20

Dr. Jan Glaser  
 Manager Reference Substances

This is a computer print and valid without signature. A signed certificate of analysis can be taken on request.