

# Certificate of Analysis

|                       |               |                  |                      |
|-----------------------|---------------|------------------|----------------------|
| Name of the product   | : Cyclo Spray |                  |                      |
| Product number        | : 97064004    | Packaging        | : 422 ml             |
| Batch number          | : 1711384     | Date of analysis | : 06-12-2017         |
| Manufacturing date    | : 11-2017     | CoA version      | : SC-LAB97064004.4.0 |
| Expiry date           | : 11-2020     | Destination      | : Hungary            |
| Batch number internal | : 959784      |                  |                      |

| DETERMINATIONS                      | SPECIFICATIONS                                | RESULTS                     |
|-------------------------------------|---|-----------------------------|
| CHARACTERS                          | Blue suspension                               | Blue suspension             |
| ODOUR                               | Characteristic odour of IPA                   | Characteristic odour of IPA |
| NETT FILL WEIGTH (g)                | 253.6 – 269.4                                 | 263.3                       |
| PARTICLE SIZE DISTRIBUTION (%)      | ≥80% < 100 µm<br>≥45% < 50 µm<br>≥15% < 20 µm | 100<br>98<br>81             |
| PRESSURE TESTING (bar)              | 2.5 - 3.5                                     | 3.0                         |
| LEAKAGE TESTING (%/year)            | < 3.5   | 0.1                         |
| DELIVERY RATE (g/s)                 | 0.9 -1.6                                      | 1.3                         |
| RESUSPENDABILITY (%)                | ≥ 90  | 99                          |
| MICROBIOLOGICAL QUALITY             | Ph.Eur.,5.1.4, Cat.2                          | Ph.Eur.,5.1.4, Cat.2        |
| IDENTIFICATION OF                   |   |                             |
| Patent blue V                       | Positive                                      | Positive                    |
| Chlortetracycline HCl               | Positive                                      | Positive                    |
| PACKAGING & LABELLING               | Conform instructions                          | Conform instructions        |
| ASSAY                               |   |                             |
| Chlortetracycline HCl (g/container) | 6.10 – 6.74                                   | 6.48                        |

Stefan van Roosmalen

  
06 DEC 2017

Qualified Person

**Conclusion : Conform specifications.**

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

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