

## CERTIFICATE OF ANALYSIS

Product: **TOP SPOT ON STRONGER 650 mg, solution for application – spot-on for dogs**

Batch No.: **81 59 25 C**

Expiry: **05.09.2020**

Date of production: **06.09.2018**

**Results of analysis:**

| Tests                                                                     | Release limits                                                                                                                                                        | Shelf-life limits   | Results                                      |
|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------------------------------|
| Appearance                                                                | Yellowish clear liquid.                                                                                                                                               |                     | conforms                                     |
| Solution volume<br>- nominal<br>- usable                                  | min. 25 ml<br>at least 25 ml                                                                                                                                          |                     | 26 ml                                        |
| Density                                                                   | 1.05 – 1.1 g/ml                                                                                                                                                       |                     | 1.08 g/ml                                    |
| Permethrin identity                                                       | Must be proved (HPLC).                                                                                                                                                |                     | conforms                                     |
| Permethrin content                                                        | 617.5 – 682.5 mg/ml                                                                                                                                                   | 585.0 – 682.5 mg/ml | 663.32 mg/ml                                 |
| Impurities<br>- individual<br>unspecified impurity<br>- sum of impurities | max. 1.0 %<br><br>max. 2.5 %                                                                                                                                          |                     | conforms<br><br>1.21 %                       |
| Butylparabene identity                                                    | Must be proved (HPLC).                                                                                                                                                |                     | conforms                                     |
| Butylparabene content                                                     | 0.95 – 1.05 mg/ml                                                                                                                                                     | 0.90 – 1.10 mg/ml   | 1.005 mg/ml                                  |
| Butylhydroxyanisole identity                                              | Must be proved (HPLC).                                                                                                                                                |                     | conforms                                     |
| Butylhydroxyanisole content                                               | 0.18 – 0.22 mg/ml                                                                                                                                                     | 0.16 – 0.22 mg/ml   | 0.213 mg/ml                                  |
| Butylhydroxytoluene identity                                              | Must be proved (HPLC).                                                                                                                                                |                     | conforms                                     |
| Butylhydroxytoluene content                                               | 0.09 – 0.11 mg/ml                                                                                                                                                     | 0.08 – 0.11 mg/ml   | 0.099 mg/ml                                  |
| Microbiological quality                                                   | Must comply.<br>TAMC (CFU/ml): $10^2$<br>TYMC (CFU/ml): $10^1$<br>Absence of <i>Staphylococcus aureus</i> in 1 ml<br>Absence of <i>Pseudomonas aeruginosa</i> in 1 ml |                     | <10 CFU/ml<br><10 CFU/ml<br>absent<br>absent |

I certify that this product has been tested in the laboratories of Bioveta a.s. and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN No. 377.



*Handwritten signature*  
.....09/01/2019  
Mgr. Hana Nezvalová  
HEAD of QC, QP