

## CERTIFICATE OF ANALYSIS

Product: **FIPRIN 402 mg, soluție spot-on pentru câini XL**

Batch No.: **09 19 A01**

Expiry: **13.01.2021**

Date of production: **14.01.2019**

### Results of analysis:

| Tests                                            | Release limits                                                                                                                                                                                                                            | Shelf-life limits         | Results                 |
|--------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-------------------------|
| Appearance                                       | Clear, yellow to yellow-green solution. Solution is as clear as water R. Solution is not more intensely yellow-coloured than reference solution Y2. Solution is not more intensely greenish-yellow-coloured than reference solution GY 1. |                           | complies                |
| Microbiological safety                           | Product must be safe.                                                                                                                                                                                                                     |                           | complies                |
| Water content                                    | max. 1.5 %                                                                                                                                                                                                                                | max 3.0 %                 | 0.64 %                  |
| Density                                          | (1.018 – 1.038) g/cm <sup>3</sup>                                                                                                                                                                                                         |                           | 1.024 g/cm <sup>3</sup> |
| Index of refraction                              | 1.40 – 1.48                                                                                                                                                                                                                               |                           | 1.435                   |
| Identity of fipronil                             | Must be proved.                                                                                                                                                                                                                           |                           | complies                |
| Fipronil content                                 | (381.90 – 422.10) mg/tube                                                                                                                                                                                                                 |                           | 388.51 mg/tube          |
| Butylhydroxyanisole identity test                | Must be proved.                                                                                                                                                                                                                           |                           | complies                |
| Determination of butylhydroxyanisole content     | (0.18 – 0.22) mg/ml                                                                                                                                                                                                                       |                           | 0.200 mg/ml             |
| Butylhydroxytoluene identity test                | Must be proved.                                                                                                                                                                                                                           |                           | complies                |
| Determination of butylhydroxytoluene content     | 0.09 – 0.11 mg/ml                                                                                                                                                                                                                         | 0.08 - 0.11 mg/ml         | 0.10 mg/ml              |
| Purity tests                                     | Fipronil impurities                                                                                                                                                                                                                       |                           |                         |
|                                                  | impurity A – max. 1.0 %                                                                                                                                                                                                                   |                           | 0.19 %                  |
|                                                  | impurity B – max. 1.0 %                                                                                                                                                                                                                   |                           | 0.22 %                  |
|                                                  | any individual undefined impurity – max. 1.0 %                                                                                                                                                                                            |                           | < 1.0 %                 |
|                                                  | sum of impurities – 2.0 %                                                                                                                                                                                                                 | sum of impurities – 4.0 % | 0.83 %                  |
| Mass uniformity of doses in multidose containers | Must comply.                                                                                                                                                                                                                              |                           | complies                |
| The average volume of usable                     | Y ± 5%<br>(Y = theoretical value of the desired extractable volume)                                                                                                                                                                       |                           | 3.925 ml                |

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. 112d.



25/02/2019  
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HEAD of QC, QP