

**CERTIFICATE OF ANALYSIS**  
**No. 144/19.02.2024**

**MILBENIN 2.5 mg/25 mg chewable tablets for small dogs and puppies**

Batch no: 29V001

Manufacturing date: 01.2024

Expiry date: 12.2025

Analysis performed in conformity with Product Specification (ST-29AUV-2022-03-EN)

| TESTS                                                                                                             | REQUIREMENTS                                                                                                                                                                                                                                                                                              | RESULTS  |
|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| Aspect, colour                                                                                                    | Round, white or almost white, evenly distributed, brownish-pigmented tablets, with bevelled edges; diameter: approx. 7 mm                                                                                                                                                                                 | Complies |
| Odour                                                                                                             | Characteristic                                                                                                                                                                                                                                                                                            | Complies |
| Average mass, mg                                                                                                  | 114.0 – 126.0 (120.0 ± 5 %)                                                                                                                                                                                                                                                                               | 120.4    |
| Identification                                                                                                    |                                                                                                                                                                                                                                                                                                           |          |
| A. by retention times<br>- milbemycin oxime A <sub>3</sub><br>- milbemycin oxime A <sub>4</sub><br>- praziquantel | The 3 principal peaks (milbemycin oxime A <sub>3</sub> , milbemycin oxime A <sub>4</sub> and praziquantel) in the chromatogram obtained with the test solution are similar in retention time and size to the 3 principal peaks in the chromatogram obtained with reference solution (a).                  | Complies |
| B. by UV spectra<br>- milbemycin oxime A <sub>3</sub><br>- milbemycin oxime A <sub>4</sub><br>- praziquantel      | The UV spectra of the 3 principal peaks (milbemycin oxime A <sub>3</sub> , milbemycin oxime A <sub>4</sub> and praziquantel) in the DAD chromatogram obtained with the test solution are similar to the UV spectra of the 3 principal peaks in the DAD chromatogram obtained with reference solution (a). | Complies |
| Water, %                                                                                                          | max. 6.0                                                                                                                                                                                                                                                                                                  | 4.97     |
| Dissolution                                                                                                       |                                                                                                                                                                                                                                                                                                           |          |
| - milbemycin oxime (A <sub>3</sub> + A <sub>4</sub> ), % after 60 min.                                            | min. 75 (Q)                                                                                                                                                                                                                                                                                               | 94.63    |
| - praziquantel, % after 60 min.                                                                                   | min. 75 (Q)                                                                                                                                                                                                                                                                                               | 95.14    |
| Assay                                                                                                             |                                                                                                                                                                                                                                                                                                           |          |
| - milbemycin oxime (A <sub>3</sub> + A <sub>4</sub> ), mg/tab.                                                    | 2.375 – 2.625 (2.500 ± 5 %)                                                                                                                                                                                                                                                                               | 2.542    |
| - praziquantel, mg/tab.                                                                                           | 23.75 – 26.25 (25.00 ± 5 %)                                                                                                                                                                                                                                                                               | 24.72    |
| Uniformity of dosage units<br>(Mass variation)                                                                    |                                                                                                                                                                                                                                                                                                           |          |
| - Acceptance value (AV)                                                                                           |                                                                                                                                                                                                                                                                                                           |          |
| - milbemycin oxime (A <sub>3</sub> + A <sub>4</sub> )                                                             | max. 15                                                                                                                                                                                                                                                                                                   | 6.6      |
| - praziquantel, mg/tab.                                                                                           | max. 15                                                                                                                                                                                                                                                                                                   | 5.3      |

| TESTS                                  | REQUIREMENTS         | RESULTS |
|----------------------------------------|----------------------|---------|
| Related substances (HPLC)              |                      |         |
| Milbemycin oxime                       |                      |         |
| - impurity G, %                        | max. 0.2             | ND      |
| - impurity E, %                        | max. 0.7             | ND      |
| - impurity H, %                        | max. 0.5             | ND      |
| - impurity I, %                        | max. 0.5             | ND      |
| - any other individual impurity, %     | max. 0.3             | ND      |
| - total impurities, %                  | max. 3.5             | ND      |
| Praziquantel                           |                      |         |
| - impurity A, %                        | max. 0.2             | ND      |
| - impurity B, %                        | max. 0.2             | < 0.05  |
| - unspecified impurities, %            | max. 0.10            | ND      |
| - total                                | max. 0.5             | < 0.05  |
| Microbiological quality*               |                      |         |
| - total aerobic microbial count, CFU/g | max. 10 <sup>3</sup> | < 10    |
| - total yeasts and moulds count, CFU/g | max. 10 <sup>2</sup> | < 10    |
| - Escherichia coli, CFU/g              | absence              | absence |

\* Analysis performed by M-TESZT Kft. (contracted analysis)

**Conclusions:** The analysed product is Milbenin 2.5 mg/25 mg chewable tablets for small dogs and puppies, which corresponds with the requirements of the Product Specification.

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