

## CERTIFICATE OF ANALYSIS

Product: **EQUIVERM DUO, pastă orală**  
Batch No.: **01 62 26 A**  
Expiry: **01.12.2021**  
Date of production: **02.12.2019**

### Results of analysis:

| Tests                                             | Release limits                                                                                                     | Shelf-life limits | Results                                        |
|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|-------------------|------------------------------------------------|
| Appearance                                        | Green paste with a characteristic odour of apples and cinnamon.                                                    |                   | complies                                       |
| Package usable volume                             | min. 7.0 ml                                                                                                        |                   | 7.8 ml                                         |
| Water content (KF)                                | max. 0.3 %                                                                                                         |                   | 0.03 %                                         |
| Microbiological safety                            | Must comply.<br>TAMC (CFU/g): 10 <sup>3</sup><br>TYMC (CFU/g): 10 <sup>2</sup><br><i>Escherichia coli</i> : absent |                   | complies<br>< 10 CFU/g<br>< 10 CFU/g<br>absent |
| Density                                           | 1.000 – 1.050 g/cm <sup>3</sup>                                                                                    |                   | 1.012 g/cm <sup>3</sup>                        |
| Ivermectin identity test                          | Must comply.                                                                                                       |                   | complies                                       |
| Determination of ivermectin content               | (19.0 – 21.0) mg/ml                                                                                                |                   | 19.6 mg/ml                                     |
| Praziquantel identity test                        | Must comply.                                                                                                       |                   | complies                                       |
| Determination of praziquantel content             | (95.0 – 105.0) mg/ml                                                                                               |                   | 101.8 mg/ml                                    |
| Butylhydroxyanisole identity test                 | Must comply.                                                                                                       |                   | complies                                       |
| Determination of butylhydroxyanisole content      | (0.18 – 0.22) mg/ml                                                                                                | 0.21 mg/ml        | 0.21 mg/ml                                     |
| Purity tests                                      |                                                                                                                    |                   |                                                |
| Ivermectin impurities                             |                                                                                                                    |                   |                                                |
| - impurities with a relative retention of 1.0-1.2 | max. 2.5 %                                                                                                         |                   | 0.2 %/ 0.6 %                                   |
| - any individual undefined impurity               | max. 1.0 %                                                                                                         |                   | complies                                       |
| - sum of impurities                               | max. 5.0 %                                                                                                         |                   | 1.2 %                                          |
| Praziquantel impurities                           |                                                                                                                    |                   |                                                |
| - any individual undefined impurity               | max. 1.0 %                                                                                                         |                   | complies                                       |
| - sum of impurities                               | max. 2.0 %                                                                                                         |                   | 1.1 %                                          |
| Particle size                                     | min. 95 % of particles ≤ 30 µm                                                                                     |                   | complies                                       |
| Injectability                                     | Must comply.                                                                                                       |                   | complies                                       |
| Viscosity                                         | 800 – 1600 mPa.s                                                                                                   |                   | 1 538 mPa.s                                    |
| Mass uniformity of doses in multidose containers  | Must comply.                                                                                                       |                   | complies                                       |

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. 102,spec.01.



  
.....20/12/2019  
Mgr. Hana Nezvalová  
HEAD of QC, QP