



## Certificate of Analysis

Certificate No.: 45912

aniMedica Herstellungs GmbH  
a LIVISTO company

|                     |                                 |                                 |                         |
|---------------------|---------------------------------|---------------------------------|-------------------------|
| Product:            | Metrovis flavour 750mg 80tab RO |                                 |                         |
| Article number:     | 00100465                        | Dosage form:                    | Tablet                  |
| Batch:              | X518.105 Split: 0               | Package size:                   | 80 tablets              |
| Quantity:           | 150 Units                       | Marketing authorisation holder: | Livisto Int'l           |
| Manufacturing date: | 01.10.2021                      | Registration number:            | 190208                  |
| Expiry date:        | 30.09.2024                      | Distributor / Importer:         | RO - BistriVet Rumänien |

| Parameter                                | Specification                                                                                                   | Result                                                |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| Appearance                               | Beige coloured, round tablets with double indentation                                                           | Beige coloured, round tablets with double indentation |
| Identity A: metronidazole (HPLC)         | Retention times of standard and sample must correspond                                                          | Corresponds to                                        |
| Identity B: metronidazole (UV)           | The spectra of reference and sample must correspond                                                             | Corresponds to                                        |
| Loss on drying                           | Max. 5,0 %                                                                                                      | 3,0 %                                                 |
| Uniformity of dosage by mass variation   | AV(10un) $\leq$ 15,0, if AV(10un) > 15,0 then AV(30un) $\leq$ 15,0; $0,75 \times M \leq X_i \leq 1,25 \times M$ | Corresponds to                                        |
| Assay: metronidazole                     | 712,5 ... 787,5                                                                                                 | 775,3 mg/Tabl.                                        |
| Impurity A                               | Max. 0,3 %                                                                                                      | < 0,1 %                                               |
| Unspecified individual impurity          | Max. 0,3 %                                                                                                      | < 0,1 %                                               |
| Total impurities                         | Max. 0,6 %                                                                                                      | < 0,1 %                                               |
| Dissolution test (T=15min.)              | Q= 85%                                                                                                          | 102 %                                                 |
| Hardness                                 | 65 ... 95 N                                                                                                     | 80 N                                                  |
| Microbiological purity: TAMC             | Max. 1000 CFU/g                                                                                                 | < 10 CFU/g                                            |
| Microbiological purity: TYMC             | Max. 100 CFU/g                                                                                                  | < 10 CFU/g                                            |
| Microbiological purity: Escherichia coli | Absence/g                                                                                                       | Absence/g                                             |

Template: 2249

The finished product has been tested in accordance with the testing instruction and is of the required quality.

15. DEZ. 2021

Date, Signature Head of Quality Control

Amtsgericht Coesfeld  
HRB-Nr. 10339  
Geschäftsführer:  
Thomas Höltker

Im Südfeld 9  
48308 Senden-Bösensell  
Deutschland

T +49 2536 33 02-0  
F +49 2536 33 02-110

www.livisto.com

Along with you



## Batch certificate

Certificate No.: 45912

aniMedica Herstellungs GmbH  
a LIVISTO company

|                     |                                 |                                 |                         |
|---------------------|---------------------------------|---------------------------------|-------------------------|
| Product:            | Metrovis flavour 750mg 80tab RO |                                 |                         |
| Article number:     | 00100465                        | Dosage form:                    | Tablet                  |
| Batch:              | X518.105 Split: 0               | Package size:                   | 80 tablets              |
| Quantity:           | 150 Units                       | Marketing authorisation holder: | Livisto Int'l           |
| Manufacturing date: | 01.10.2021                      | Registration number:            | 190208                  |
| Expiry date:        | 30.09.2024                      | Distributor / Importer:         | RO - BistriVet Rumänien |

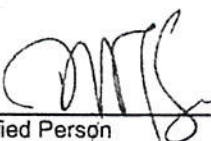
I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing and quality control instructions. The batch processing, packaging and analytical documentation has been reviewed and is in full compliance with GMP guidelines. All deviations were evaluated before batch release.

This batch has the required quality and

- ☐ is released for delivery  
☒ is released for the market

Remarks:

Four horizontal lines for handwritten remarks, each with a diagonal slash through it.

15.12.21   
Date, Signature Qualified Person

- ☒ Dr. Hans-Jörg Lange    ☐ Gudrun Pruszeit    ☐ Dr. Jürgen Schlüter    ☐ Dr. Bernd Manfred Müller  
☐ Ulrich Kontny

Amtsgericht Coesfeld  
HRB-Nr. 10339  
Geschäftsführer:  
Thomas Höltker

Im Südfeld 9  
48308 Senden-Bösensell  
Deutschland

T +49 2536 33 02-0  
F +49 2536 33 02-110

[www.livisto.com](http://www.livisto.com)

Along with you