



aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 47584

Product:	Metrovis flavour 250mg 100tab RO	Dosage form:	Tablet
Article number:	00100464	Package size:	100 tablets
Batch:	X421.206 Split: 0	Marketing authorisation holder:	Livisto Int'l
Quantity:	200 Units	Registration number:	190207
Manufacturing date:	01.09.2021	Distributor / Importer:	RO - BistriVet Rumänien
Expiry date:	31.08.2024		

Parameter	Specification	Result
Appearance	Beige coloured, round tablets with double indentation	complies
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 %	2,3 %
Uniformity of dosage by mass variation	$AV(10un) \leq 15,0$, if $AV(10un) > 15,0$ then $AV(30un) \leq 15,0$; $0,75 \times M \leq X \leq 1,25 \times M$	Corresponds to
Assay: metronidazole	237,5 ... 262,5	245,1 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%	99%
Hardness	35 ... 70 N	57 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

Template: 2236

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

25. FEB. 2022

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Hölter

Im Südfeld 9
48308 Senden-Bösensell
Deutschland

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Along with you



Batch certificate

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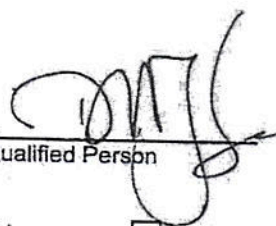
I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing 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 crossed out with a diagonal line.

25.02.2022 

Date, Signature Qualified Person

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

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