

Certificate of Analysis

Certificate No.: 44339

Product:	Metrovis flavour 250mg 100tab RO		
Article number:	00100464	Dosage form:	Tablet
Batch:	T681.117 Split: 0	Package size:	100 tablets
Quantity:	160 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	01.10.2020	Registration number:	190207
Expiry date:	30.09.2023	Distributor / Importer:	RO - BistriVet Rumänien

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 %	2,4 %
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	237,5 ... 262,5	247,0 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%	98%
Hardness	35 ... 70 N	48 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	absent

Template: 2236

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

02. NOV. 2021



Date, Signature Head of Quality Control

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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:


Date, Signature Qualified Person

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