

Certificate of Analysis

Certificate No.: 28809

Product: Metrovis flavour 100mg 100tab RO

Dosage form: Anderes

Product: 00100463

Package size: XXg (Tabletten)

Batch: S460.109 Split: 0

Marketing authorisation holder: Livisto Int'l

Quantity: 300 Units

Registration number:

Manufacturing date: 01.09.2019

Expiry date: 31.08.2021

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 %	2,1 %
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	95,0 ... 105,0	98,1 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%	100
Hardness	15 ... 30 N	17 N
Microbiological purity: TAMC	Max. 1000	10 CFU/g
Microbiological purity: TYMC	Max. 100	10 CFU/g
Microbiological purity: Escherichia coli	Absence/g	absence

Template: 2225

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

21. APR. 2020

Date, Signature Head of Quality Control



aniMedica Herstellungs GmbH
a LIVISTO company

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:

2242 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange

☐ Gudrun Prußeit

☐ Dr. Jürgen Schlüter

