

Certificate of Analysis

Certificate No.: 28072

Product: Metrovis flavour 750mg 80tab RO

Dosage form: Anderes

Package size: XXg (Tabletten)

Product: 00100465

Marketing authorisation holder: Livisto Int'l

Batch: T078.108 Split: 0

Registration number:

Quantity: 120 Units

Manufacturing date: 01-02-20

Expiry date: 31-01-22

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	712,5 ... 787,5	737,3 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%	99%
Hardness	65 ... 95 N	88 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: 2249

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

11. 01. 2020



Date, Signature Head of Quality Control



aniMedica Herstellungs GmbH
a LIVISTO company

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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 with a diagonal slash through it.

25.03.22

Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange

☐ Gudrun Pruß

☐ Dr. Jürgen Schlüter

☐