

CERTIFICATE OF ANALYSIS

Product: Metrovis flavour 250mg 100tab
RO
Dosage form: tablets
Batch No.: T077.106-
Manufac. Date: 02/2020

Testing Instruction: SFP00308-01
Expiry Date: 01/2022

Parameter	Specification	Result
Appearance	Beige coloured, round tablets with double indentation	conforms
Identity A: metronidazole (HPLC)	Retention times of standard and sample must correspond	conforms
Identity B: metronidazole (UV)	The spectra of reference and sample must correspond	conforms
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; $0,75 \times M \leq X_i \leq 1,25 \times M$	conforms
Assay metronidazole	237,5 – 262,5 mg/Tabl.	249,3 mg/Tabl.
Dissolution test (T=15min.)	Q= 85%	102%
Hardness	35 – 70 N	43 N
Related substances		
Impurity A	max. 0.3%	<0.1%
Unspecified individual impurity	max. 0.3%	<0.1%
Total impurities	max. 0.6%	<0.1%
Microbiological impurity		
TAMC	< 1000 CFU/g	10 CFU/g
TYMC	< 100 CFU/g	10 CFU/g
Escherichia coli	absent/g	absent/g

"I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/ manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation as layed down in the manufacturing and quality control instructions which have been approved by the Marketing Authorisation holder or Contract giver.
The batch processing, packaging and analysis records were reviewed and found to be in compliance in GMP."

Date of issue: 2020-03-25

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Höltker

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- Qualified Person -

Along with you



aniMedica Herstellungs GmbH
a LIVISTO company

Batch certificate

Certificate No.: 28103

Product:	Metrovis flavour 250mg 100tab RO	Dosage form:	Anderes
		Package size:	XXg (Tabletten)
Product	00100464	Marketing authorisation holder:	Livisto Int'l
Batch:	T077.106 Split: 1	Registration-No.:	
Quantity:	131 Units		
Manufacturing	01-02-20		
Expiry date:	31-01-22		

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 with diagonal slashes, indicating a signature or stamp area.

250326 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange

☐ Gudrun Prußeit

☐ Dr. Jürgen Schlüter

☐