

Certificate of Analysis

Certificate No.: 50115

Product:	Metrovis flavour 100mg 100tab RO		
Article number:	00100463	Dosage form:	Tablet
Batch:	Y290.101 Split: 0	Package size:	100 tablets
Quantity:	200 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	01.05.2022	Registration number:	190206
Expiry date:	30.04.2025	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 %	2,8 %
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	100,0 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%	102%
Hardness	15 ... 30 N	20 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: 2225

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

03. AUG. 2022

Date, Signature Head of Quality Control