

Certificate of Analysis

Certificate No.: 40093

Product:	Boflox Flavour 20mg 100er RO		
Article number:	86089	Dosage form:	Tablet
Batch:	12303607 Split: 0	Package size:	100 tablets
Quantity:	199 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	22.02.2021	Registration number:	15999/4 170022 6/2021
Expiry date:	31.01.2026	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Beige round tablets, brown speckled, cross-snap-tab	Beige round tablets, brown speckled, cross-snap-tab
Batch packaging record	batch packaging record complies	Corresponds to
Diameter	8,8 ... 9,4 mm	9,0 mm
Height	4,0 ... 4,8 mm	4,4 mm
Average mass	266 ... 294 mg	278 mg
Uniformity of dosage by mass variation	Must correspond to Ph. Eur. 2.9.40	Corresponds to
Acceptance value (AV)	Max. 15,0	1,6
Hardness	40 ... 100 N	76 N
Disintegration with disc	Max. 15 min	2 min
Acceptance level dissolution	Must correspond to Ph. Eur. 2.9.3	Corresponds to
Dissolution	After 30 min.: 80% Q	104,7%
Identity: marbofloxacin	Retention time and UV spectra of standard and sample must correspond	Corresponds to
Assay: marbofloxacin	19,0 ... 21,0	19,6 mg/Tabl.
Impurity D	Max. 1,0 %	< 0,1 %
Impurity F	Max. 1,0 %	< 0,1 %
Unknown impurity, single	Max. 1,0 %	< 0,1 %
Total impurities	Max. 1,5 %	< 0,1 %
Microbiological purity: TAMC	Max. 1000	< 1000 CFU/g
Microbiological purity: TYMC	Max. 100	< 100 CFU/g
Microbiological purity: Escherichia coli	Absent/g	Absent/g

Template: 1346

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

28. MAI 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:

Four horizontal lines for remarks, each with a blue diagonal slash mark.


Date, Signature Qualified Person

- ☒ Dr. Hans-Jörg Lange ☐ Gudrun Prußzeit ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller ☐