



aniMedica GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 26855

Product: Boflox Flavour 80mg 72er RO

Dosage form:

Package size: XXg (Tabletten)

Product: 86090

Marketing authorisation holder:

Batch: 19290002 Split: 0

Registration number:

Quantity: 324 Piece

Manufacturing date: 01-12-19

Expiry date: 30-11-22

Parameter	Specification	Result
Appearance	beige, oblong tablets, brown speckled, with breaking notch on both side	beige, oblong tablets, brown speckled, with breaking notch on both side
Batch packaging record	batch packaging record complies	Corresponds to
Length	20,2 ... 21,1 mm	20,7 mm
Breadth	8,9 ... 9,3 mm	9,2 mm
Height	6,6 ... 7,4 mm	7,1 mm
Average weight	1064 ... 1176 mg	1122 mg
Uniformity of dosage units (mass)	mind. 18 T. < +/- 5,0% ; max. 2 T. > +/- 5,0% ; < +/- 10,0% ; no T. > +/- 10,0%	Corresponds to
Acceptance value (AV)	AV max. 15,0	1,1
Resistance to crushing	100 ... 200 N	136 N
Disintegration (with disc)	Max. 15,0 min	1,0 min
Dissolution in 30 min	Min. 80 %	104 %
Identity Marbofloxacin	Retention time and UV-spectrum of reference and sample complies	Corresponds to
Assay Marbofloxacin	76,0 ... 84,0 mg	78,6 mg
Impurity D	Max. 1,0 %	< 0,1 %
Impurity F	Max. 1,0 %	< 0,1 %
Unknown impurity, single	Max. 1,0 %	< 0,1 %
Sum of impurities	Max. 1,5 %	< 0,1 %
Microbiological purity: TAMC	Max. 1000 KBE/g	< 1000 KBE/g
Microbiological purity: TYMC	Max. 100 KBE/g	< 100 KBE/g
Microbiological purity: Escherichia coli	Max. 0 KBE/g	0 KBE/g



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Parameter	Specification	Result
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Template: 1340

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


20. FEB. 2020
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.

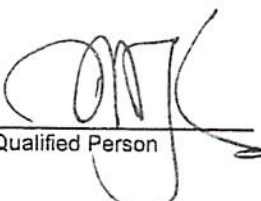
This batch has the required quality and

☐ is released for delivery

☒ is released for the market

Annotations:

_____/_____/_____/_____/

2022 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange

☐ Gudrun Prußeit

☐ Dr. Jürgen Schlüter

☐