



aniMedica GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 25880

Product:	Boflox Flavour 20mg 100er RO	Dosage form:	
		Package size:	XXg (Tabletten)
Product:	86089	Marketing authorisation holder:	
Batch:	18273726 Split: 0	Registration number:	
Quantity:	216 Piece		
Manufacturing date:	01-11-18		
Expiry date:	31-10-21		

Parameter	Specification	Result
Appearance	beige, round tablet, brown spotted cruciform break groove	beige, round tablet, brown spotted cruciform break groove
Batch packaging record	batch packaging record complies	Corresponds to
Diameter	8,8 ... 9,4 mm	9,0 mm
Height	4,0 ... 4,8 mm	4,3 mm
average weight	266 ... 294 mg	281 mg
Uniformity of mass	mind. 18 T. lighter +/- 5,0% ; max. 2 T. heavier +/- 5,0% and lighter +/- 10,0% ; no T. heavier/equalier + 10,0%	Corresponds to
Uniformity of dosage units	must comply to Ph. Eur. 2.9.40	complies
Acceptance value (AV)	AV max. 15,0	4,2
disintegration with disk	Max. 15 min	3 min
Dissolution in 30 min	Min. 80 %	101 %
Identity	Retention time and UV-Spectrum complies	Corresponds to
Assay	19,0 ... 21,0 mg	19,3 mg
Impurity D	Max. 1,0 %	< 0,1 %
Impurity F	Max. 1,0 %	< 0,1 %
Unknown impurities, single	Max. 1,0 %	< 0,1 %
Summe Verunreinigungen	Max. 1,5 %	< 0,1 %
Microbial purity: TAMC	Max. 1000 KBE/g	< 1000 KBE/g
Microbial purity: TYMC	Max. 100 KBE/g	< 100 KBE/g
Microbial purity: Escherichia coli	Max. 0 KBE/g	0 KBE/g

Template: 1346

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

23. JAN. 2020

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 7210
Geschäftsführer:
Armin Thur
Dr. Enno Gottschalk

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Along with you



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Batch certificate

Certificate No.: 25880

Product: Boflox Flavour 20mg 100er RO

Dosage form:

Package size: XXg (Tabletten)

Product 86089

Marketing authorisation holder:

Batch: 18273726 Split: 0

Registration-No.:

Quantity: 216 Piece

Manufacturing 01-11-18

Expiry date: 31-10-21

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:

27.12.2018 [Signature]

27.12.2018 [Signature]

Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange

☐ Gudrun Pruß

☐ Dr. Jürgen Schlüter

☐