

Certificate of Analysis

Certificate No.: 24569

Product: Boflox Flavour 20mg 100er RO Manufacturing date: 01-11-18
Product-No.: 86089 Expiry date: 31-10-21
Batch-No.: 18273717
Split: 0
Quantity: 108 Unit(s)

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

Certificate of Analysis

Certificate No.: 24569

Product: Boflox Flavour 20mg 100er RO

Manufacturing date: 01-11-18

Product-No.: 86089

Expiry date: 31-10-21

Batch-No.: 18273717

Split: 0

Quantity: 108 Unit(s)

Parameter	Specification	Result
-----------	---------------	--------

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

Hereby it is confirmed for the named batch, that the above information is authentic and accurate. The batch was manufactured and tested in accordance to the GMP requirements and the current authorized procedures for manufacturing and testing.

During the manufacture and testing

☒ no deviations/irregularities have been observed.

☐ the following deviations/irregularities have been observed:

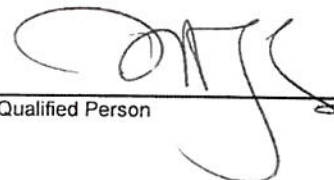
These deviations/irregularities do not affect the quality of the product, because

The named batch has the required quality and is released

☐ for dispatch

☒ for the market

Comments:

25.11.18 

Date, Signature Qualified Person