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CERTIFICATE OF ANALYSIS

Product: Boflox flavour 80mg 72er RO
Dosage form: tablets
Batch No.: 18273602
Manufac. Date: 11/2018

Manufacturer: Artesan
Testing Instruction: SFP00169-01
Expiry Date: 10/2021

Parameter	Specification	Result
Appearance	Beige oblong tablets, brown speckled, with breaking notch on both sides	conforms
Length	20.2 – 21.1 mm	20.7 mm
Tablet breadth	8.9 – 9.3 mm	9.1 mm
Height	6.6 – 7.4 mm	7.1 mm
Average weight	1064 – 1176 mg	1122.3 mg
Uniformity of dosage units	conform to Ph. Eur. 2.9.40	conforms
Acceptance value (AV)	AV max. 15.0	1.3
Resistance to crushing	100 N ≤ X ≤ 200 N	155 N
Disintegration with disc	≤ 15.0 min	1.0 min
Acceptance level dissolution	conform to Ph. Eur. 2.9.3	conforms
Dissolution	min. 80% Q / 30 min	99.2 %
Identity Marbofloxacin	Retention times and UV-spectrum complies	conforms
Assay Marbofloxacin	76.0 – 84.0 mg	78.8 mg
Related substances		
Impurity D	max.1.0%	<0.12%
Impurity F	max.1.0%	<0.12%
Unknown impurities, single	max.1.0%	<0.12%
Total impurities	max.1.5%	<0.12%
Microbiological impurity		
TAMC	< 1000 CFU/g	< 1000 CFU/g
TYMC	< 100 CFU/g	< 100 CFU/g
Escherichia coli	Absent/g	Absent/g

"I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/ manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation as layed down in the manufacturing and quality control instructions which have been approved by the Marketing Authorisation holder or Contract giver.
The batch processing, packaging and analysis records were reviewed and found to be in compliance in GMP."

Date of issue:

Amtsgericht Coesfeld
HRB-Nr. 7210
Geschäftsführer:
Armin Thur

- Qualified Person -

Along with you