



LIVISTO

aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 50687

Product: Ficoxil 227mg 100tab. RO
Article number: 00101023 Dosage form: Tablet
Batch: 22D19 Split: 0 Package size: 100 tablets
Quantity: 299 Units Marketing authorisation holder: Livisto Int'l
Manufacturing date: 01.06.2022 Registration number:
Expiry date: 31.03.2025 Distributor / Importer:

Parameter	Specification	Result
Appearance	Biconvex rosaceous round tablets of 15 mm with a double groove on one side without inscriptions	Biconvex rosaceous round tablets of 15 mm with a double groove on one side without inscriptions
Uniformity of mass	Min. 18 of 20 tablets: 95 - 105 % Max. 2 of 20 tablets: 90 - 110 %	corresponds to
Hardness	70 ... 165 N	113 N
Disintegration time	Max. 15 min	< 1 min
Loss on drying	Max. 5 %	4 %
Friability	Max. 1,0 %	0,4 %
Dissolution	At 30 Min: ≥ 90 % (Q = 85%)	93 - 96 %
Uniformity of dosage units	L1 $\leq 15,0$ L2 $\leq 25,0$	corresponds to
Identity: firocoxib	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Assay: firocoxib	95,0 ... 105,0 %	99,9 %
Assay: firocoxib	215,65 ... 238,35	226,67 mg/Tabl.
Any impurity, single	Max. 1,0 %	< 0,1 %
Any impurities	Max. 2,0 %	< 0,1 %

Template: 3458

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

01. SEP. 2022

Date: Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Hölter

Im Südfeld 9
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www.livisto.com

Along with you



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Batch certificate

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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:

n.a.

03.09.2022 *Stephan Bruns*

Date, Signature Qualified Person

- ☐ Dr. Hans-Jörg Lange ☒ Stephan Bruns ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller ☐ Ulrich Kontny

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