



LIVISTO

aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 50903

Product: Ficoxil 227mg 30tab. RO
Article number: 00101024
Batch: 22D21 Split: 0
Quantity: 284 Units
Manufacturing date: 01.07.2022
Expiry date: 31.03.2025
Dosage form: Tablet
Package size: 30 tablets
Marketing authorisation holder: Livisto Int'l
Registration number:
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	110 N
Disintegration time	Max. 15 min	< 1 min
Loss on drying	Max. 5 %	4 %
Friability	Max. 1,0 %	0,5 %
Dissolution	At 30 Min: ≥ 90 % (Q = 85%)	S1: 92 - 96 %
Uniformity of dosage units	L1 $\leq 15,0$ L2 $\leq 25,0$	3,0
Identity: firocoxib	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Assay: firocoxib	95,0 ... 105,0 %	101,4 %
Assay: firocoxib	215,65 ... 238,35	230,13 mg/Tabl.
Any impurity, single	Max. 1,0 %	< 0,1 %
Total impurities	Max. 2,0 %	< 0,1 %

Template: 3457

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

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Höltker

Im Südfeld 9
48308 Senden-Bösensell
Deutschland

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www.livisto.com

Along with you



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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:

17.06.

15.09.2022 *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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