



LIVISTO

aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 50792

Product: Ficoxil 57mg 30tab. RO
Article number: 00101026
Batch: 22D18 Split: 0
Quantity: 212 Units
Manufacturing date: 01.06.2022
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 9 mm with a double groove on one side without inscriptions	Biconvex rosaceous round tablets of 9 mm with a double groove on one side without inscriptions
Uniformity of mass	Min. 18 of 20 tablets: 92,5 - 107,5 % Max. 2 of 20 tablets: 85 - 115 %	corresponds to
Hardness	40 ... 135 N	93 N
Disintegration time	Max. 15 min	< 4 min
Loss on drying	Max. 5 %	4 %
Friability	Max. 1,0 %	0,4 %
Dissolution	At 30 Min: ≥ 90 % (Q = 85%)	S1: 91 - 95 %
Uniformity of dosage units	L1 $\leq 15,0$ L2 $\leq 25,0$	3,2
Identity: firocoxib	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Assay: firocoxib	95,0 ... 105,0 %	99,2 %
Assay: firocoxib	54,15 ... 59,85	56,54 mg/Tabl.
Any impurity, single	Max. 1,0 %	< 0,1 %
Total impurities	Max. 2,0 %	< 0,1 %
Microbiological purity: TAMC	Max. 1000 CFU/g	< 1000 CFU/g
Microbiological purity: TYMC	Max. 100 CFU/g	< 100 CFU/g
Microbiological purity: Escherichia coli	Absent/g	Corresponds to

Template: 3453

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

07. SEP. 2022

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Höltker

Im Südfeld 9
48308 Senden-Bösensell
Deutschland

T +49 2536 33 02-0
F +49 2536 33 02-110

www.livisto.com

Along with you



aniMedica Herstellungs GmbH
a LIVISTO company

Batch certificate

Certificate No.: 50792

Product:	Ficoxil 57mg 30tab. RO	Dosage form:	Tablet
Article number:	00101026	Package size:	30 tablets
Batch:	22D18 Split: 0	Marketing authorisation holder:	Livisto Int'l
Quantity:	212 Units	Registration number:	
Manufacturing date:	01.06.2022	Distributor / Importer:	
Expiry date:	31.03.2025		

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:

no.

12.09.2022 *Stephan Bruns*
Date, Signature Qualified Person

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