



aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 68664

Product: Ficoxil 227mg 30tab. PT/RO
Article number: 00101272 Dosage form: Tablet
Batch: 25B73 Split: 0 Package size: 30 tablets
Quantity: 595 Units Marketing authorisation holder: Livisto Int'l
Manufacturing date: 01.03.2025 Registration number:
Expiry date: 31.01.2029 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	115 N
Disintegration time	Max. 15 min	< 2 min
Loss on drying	Max. 5 %	4 %
Friability	Max. 1,0 %	0,6 %
Dissolution	At 30 Min: ≥ 90 % (Q = 85%)	S1: 95%; 92 - 98 %
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 %	100,6 %
Assay: firocoxib	215,65 ... 238,35	228,33 mg/Tabl.
Any impurity, single	Max. 1,0 %	< 0,3 %
Total impurities	Max. 2,0 %	< 0,3 %
Microbiological purity: TAMC	Max. 1000 CFU/g	< 1000 CFU/g
Microbiological purity: TYMC	Max. 100 CFU/g	< 10 CFU/g
Microbiological purity: Escherichia coli	Absent/g	Corresponds to

Template: 3672

TAMC, TYMC and Escherichia coli are tested periodically every 10th batch but at least once a year.
The finished product has been tested in accordance with the testing instruction and is of the required quality.

23. APR. 2025

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 10339
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