

Certificate of Analysis

Certificate No.: 68618

Product: Ficoxil 57mg 30tab. PT/RO
Article number: 00101274 Dosage form: Tablet
Batch: 25B71 Split: 0 Package size: 30 tablets
Quantity: 322 Units Marketing authorisation holder: Livisto Int'l
Manufacturing date: 01.02.2025 Registration number:
Expiry date: 31.01.2029 Distributor / Importer:

Parameter	Specification	Result
Appearance	Biconvex rosaceous round tablets of 9 mm with a double groove on one side without inscriptions	corresponds to
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	94 N
Disintegration time	Max. 15 min	< 3 min
Loss on drying	Max. 5 %	4 %
Friability	Max. 1,0 %	0,5 %
Dissolution	At 30 Min: ≥ 90 % (Q = 85%)	93%
Uniformity of dosage units	L1 $\leq 15,0$ L2 $\leq 25,0$	2,9
Identity: firocoxib	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Assay: firocoxib	95,0 ... 105,0 %	98,7 %
Assay: firocoxib	54,15 ... 59,85	56,25 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: 3664

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
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

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