

Certificate of Analysis

Certificate No.: 31860

Product:	Animeloxan 20mg/ml inj 100ml EP RO	Dosage form:	Solution for injection
		Package size:	100ml
Product:	00100531	Marketing authorisation holder:	aniMedica GmbH
Batch:	20016802 Split: 0	Registration number:	190221
Quantity:	1.100 Units		
Manufacturing date:	26.05.2020		
Expiry date:	30.04.2023		

Parameter	Specification	Result
Appearance	Clear pale yellow solution, free of visible particles	complies
pH	6,5 ... 9,5	8,9
Transmittance at 650nm	Min. 97 %	101 %
Extractable volume	Min. 100 %	102 %
Identity: meloxicam	Retention times and UV spectra of standard and sample must correspond	Corresponds to
Assay: meloxicam	19,0 ... 21,0 mg/ml	20,1 mg/ml
Impurity: 5-methylthiazol-2-ylamine	Max. 0,3 %	< 0,1 %
Any other impurity	Max. 0,5 %	< 0,1 %
Total impurities	Max. 1,0 %	< 0,1 %
Sterility	Sterile	Corresponds to

Template: 2558

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

29. JULI 2020



Date, Signature Head of Quality Control



aniMedica GmbH
a LIVISTO company

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:

280726

Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange ☐ Gudrun Prusseit

☐ Dr. Jürgen Schlüter

