

Certificate of Analysis

Certificate No.: 39565

Product:	Animeloxan 20mg/ml inj 100ml EP RO		
Article number:	00100531	Dosage form:	Solution for injection
Batch:	21021701 Split: 0	Package size:	100ml
Quantity:	1.000 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	21.04.2021	Registration number:	190221
Expiry date:	31.03.2024	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear pale yellow solution, free of visible particles	complies
I	6,5 ... 9,5	9,0
Transmittance at 650nm	Min. 97 %	99 %
Extractable volume	Min. 100 %	102 %
Identity: meloxicam	Retention times and UV spectrum of standard and sample must correspond	Corresponds to
Assay: meloxicam	19,0 ... 21,0 mg/ml	20,5 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.

12. MAI 2021

Date, Signature Head of Quality Control

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:


Date, Signature Qualified Person

- ☒ Dr. Hans-Jörg Lange ☐ Gudrun Pruß ☐ Dr. Jürgen Schlüter ☐