

Certificate of Analysis

Certificate No.: 47408

Product:	Menbutil 100mg/ml inj 100ml EP RO		
Article number:	49025	Dosage form:	Solution for injection
Batch:	22008807 Split: 0	Package size:	100ml
Quantity:	1.000 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	20.01.2022	Registration number:	150417
Expiry date:	31.12.2023	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear, slightly yellow solution, GY2 - GY6/B4 - B6, practically free of particles	Complies
pH	8,6 ... 9,6	9,2
Absolute density	1,030 ... 1,035 g/ml	1,032 g/ml
Refractive index	1,3600 ... 1,3700	1,3635
Extractable volume	Min. 100 ml	101,7 ml
Identity: menbutone	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Identity: chlorocresol	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Identity: sodium metabisulphite	Colour reaction must correspond	Corresponds to
Assay: menbutone	95,0 ... 105,0 mg/ml	96,4 mg/ml
Assay: chlorocresol	1,9 ... 2,1 mg/ml	1,9 mg/ml
Assay: edetic acid	1,9 ... 2,1 mg/ml	2,0 mg/ml
Assay: sodium metabisulphite	1,8 ... 2,1 mg/ml	1,9 mg/ml
Unknown impurity, single	Max. 0,5 %	< 0,1 %
Total impurities	Max. 1 %	< 1 %
Sterility	Sterile	Corresponds to

Template: 994

Assay edetic acid is tested periodically every 5th 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.

22. FEB. 2022
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:

28.12.22 
Date, Signature Qualified Person

- ☒ Dr. Hans-Jörg Lange ☐ Gudrun Pruß ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller
- ☐ Ulrich Kontny