

Batch certificate

Certificate No.: 24809

Product:	Menbutil 100mg/ml inj 100ml EP RO		
Article number:	49025	Dosage form:	Solution for injection
Batch:	24004501 Split: 0	Package size:	100ml
Quantity:	1.008 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	10.01.2024	Registration number:	150417
Expiry date:	31.12.2025	Distributor / Importer:	RO - BistriVet Rumänien

Certification statement:

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Remarks:

n.a.

23. MAI 2024



Date, Signature Qualified Person

☐ Dr. Hans-Jörg Lange ☒ Stephan Bruns ☐ Dr. Jürgen Schlüter ☐ Ulrich Kontny

Certificate of Analysis

Certificate No.: 62074

Product:	Menbutil 100mg/ml inj 100ml EP RO		
Article number:	49025	Dosage form:	Solution for injection
Batch:	24004501 Split: 0	Package size:	100ml
Quantity:	1,008 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	10.01.2024	Registration number:	150417
Expiry date:	31.12.2025	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear, slightly yellow solution, GY2 - GY6/B4 - B6, practically free of particles	Clear, slightly yellow solution, GY2, practically free of particles
pH	8,6 ... 9,6	9,1
Absolute density	1,030 ... 1,035 g/ml	1,032 g/ml
Refractive index	1,3600 ... 1,3700	1,3632
Extractable volume	Min. 100 ml	102,0 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	98,7 mg/ml
Assay: chlorocresol	1,9 ... 2,1 mg/ml	2,0 mg/ml
Assay: edetic acid	1,9 ... 2,1 mg/ml	2,0 mg/ml
Assay: sodium metabisulphite	1,8 ... 2,1 mg/ml	1,8 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.

21. MAI 2024



Date, Signature Head of Quality Control