

Certificate of Analysis

Certificate No.: 68396

Product:	Menbutil 100mg/ml inj 100ml EP RO		
Article number:	49025	Dosage form:	Solution for injection
Batch:	25015103 Split: 0	Package size:	100ml
Quantity:	1,008 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	14.03.2025	Registration number:	150417
Expiry date:	28.02.2027	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 - GY6/B4 - B6, practically free of particles
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	1,3639
Extractable volume	Min. 100 ml	102,5 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	98,9 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	2,0 mg/ml
Unknown impurity, single	Max. 0,5 %	0,0 %
tal impurities	Max. 1 %	0 %
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.

07. APR. 2025

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 7210
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