

Certificate of Analysis

Certificate No.: 65241

Product:	Menbutil 100mg/ml inj 100ml EP RO		
Article number:	49025	Dosage form:	Solution for injection
Batch:	24015109 Split: 0	Package size:	100ml
Quantity:	1,008 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	24.07.2024	Registration number:	150417
Expiry date:	30.06.2026	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, GY5, practically free of particles
pH	8,6 ... 9,6	9,1
Absolute density	1,030 ... 1,035 g/ml	1,033 g/ml
Refractive index	1,3600 ... 1,3700	1,3640
Extractable volume	Min. 100 ml	102,2 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	97,3 mg/ml
Assay: chlorocresol	1,9 ... 2,1 mg/ml	1,9 mg/ml
Assay: edetic acid	1,9 ... 2,1 mg/ml	Periodic test, no result
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.

20. SEP. 2024

Date, Signature Head of Quality Control