

Certificate of Analysis

Certificate No.: 26967

Product: Menbutil 100mg/ml inj 100ml EP RO

Dosage form:

Package size: 100ml

Product: 49025

Marketing authorisation holder:

Batch: 19035404 Split: 0

Registration number: 150417

Quantity: 1.000 Piece

Manufacturing date: 20-05-19

Expiry date: 30-04-21

Parameter	Specification	Result
Appearance	clear, light yellow solution GY2-GY6 / B4- B6, particle free	clear, light yellow solution GY5, particle free
pH	8,6 ... 9,6	9,1
Absolute density	1,030 ... 1,035 g/ml	1,032 g/ml
Refraction index	1,3600 ... 1,3700	1,3644
Filling quantity	Min. 100 ml	102 ml
Identity Menbuton	Retention times and UV-Spectrum of standard and sample must be identical	Corresponds to
Identity Chlorocresol	Retention times and UV-Spectrum of standard and sample must be identical	Corresponds to
Identity Natriummetabisulfite	conforms	Corresponds to
Assay Menbuton	95,0 ... 105,0 mg/ml	98,5 mg/ml
Assay Chlorocresol	1,9 ... 2,1 mg/ml	1,9 mg/ml
Assay edetic	1,9 ... 2,1 mg/ml	Periodic test, no result
Assay Sodium metabisulfite	1,8 ... 2,1 mg/ml	1,9 mg/ml
Sterility	sterile	Corresponds to
Unkown impurity, single	Max. 0,5 %	< 0,1 %
Unkown impurity, total	Max. 1 %	< 1 %

Template: 994

The finished product has been tested in accordance with the testing instruction and is of the required quality.

 25. FEB. 2020
Date, Signature Head of Quality Control



aniMedica GmbH
a LIVISTO company

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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

Annotations:

26226 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange

☐ Gudrun Pruß

☐ Dr. Jürgen Schlüter

☐