

Certificate of Analysis

Certificate No.: 21240

Product:	Menbutil 100mg/ml inj 100ml EP RO	Manufacturing date:	12-03-19
Product-No.:	49025	Expiry date:	28-02-21
Batch-No.:	19025502		
Split:	0		
Quantity:	1.000 Unit(s)		

Parameter	Specification	Result
Appearance	clear, light yellow solution GY2-GY6 / B4-B6, particle free	clear, light yellow solution GY4, particle free
Batch packaging record	batch packaging record complies	Corresponds to
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	1,3652
Filling quantity	Min. 100 ml	101 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	97,9 mg/ml
Assay Chlorocresol	1,9 ... 2,1 mg/ml	2,0 mg/ml
Assay edetic	1,9 ... 2,1 mg/ml	2,0 mg/ml
Assay Sodium metabisulfite	1,8 ... 2,1 mg/ml	1,8 mg/ml
Sterility	sterile	Corresponds to
Unkown impurity, single	Max. 0,5 %	0,0 %
Unkown impurity, total	Max. 1 %	0 %

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

Hereby it is confirmed for the named batch, that the above information is authentic and accurate. The batch was manufactured and tested in accordance to the GMP requirements and the current authorized procedures for manufacturing and testing.

During the manufacture and testing

☒ no deviations/irregularities have been observed.

☐ the following deviations/irregularities have been observed:

These deviations/irregularities do not affect the quality of the product, because

The named batch has the required quality and is released

☐ for dispatch

☒ for the market

Comments:

150715
Date, Signature Qualified Person