

Certificate of Analysis

Certificate No.: 14493

Product:	Menbutil 100mg/ml inj 100ml EP RO	Manufacturing date:	17-04-18
Product-No.:	49025	Expiry date:	31-03-20
Batch-No.:	18152002		
Split:	0		
Quantity:	616 Unit(s)		

Parameter	Specification	Result
Appearance	clear, light yellow solution GY2-GY6 / B4-B6, particle free	clear, light yellow solution, GY5, 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	1,3632
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	97,5 mg/ml
Assay Chlorocresol	1,9 ... 2,1 mg/ml	2,0 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 %