

Certificate of Analysis

Certificate No.: 19014

Product:	Suifertil 4mg/ml solution 1000ml RO	Dosage form:	Oral solution
Article number:	49330	Package size:	1000ml
Batch:	22020116 Split: 0	Marketing authorisation holder:	aniMedica GmbH
Quantity:	100 Units	Registration number:	170529
Manufacturing date:	01.02.2022	Distributor / Importer:	RO - BistriVet Rumänien
Expiry date:	31.01.2027		

Parameter	Specification	Result
Appearance	A clear, yellow solution	A clear, yellow solution
Absolute density	0,9200 ... 0,9250 g/ml	0,9207 g/ml
Refractive index	1,4700 ... 1,4800	1,4757
Net fill volume $\geq 100,0\%$	Min. 98 %	$> 98 \%$
Net fill volume $\leq 98,5\%$	Max. 2 %	$< 2 \%$
Net fill volume $\leq 97\%$	Max. 0 %	0 %
Identity: altrenogest	Retention time of standard and sample must correspond	Corresponds to
Identity: butylhydroxyanisole	Retention time of standard and sample must correspond	Corresponds to
Identity: butylhydroxytoluene	Retention time of standard and sample must correspond	Corresponds to
Assay: altrenogest	3,8 ... 4,2 mg/ml	4,1 mg/ml
Assay: butylhydroxyanisole	Max. 0,077 mg/ml	0,062 mg/ml
Assay: butylhydroxytoluene	Max. 0,077 mg/ml	0,069 mg/ml
Any known impurity, single	Max. 1,0 %	0,0 %
Any unknown impurity, single	Max. 1,0 %	$< 0,1 \%$
total impurities	Max. 3 %	$< 1 \%$
Microbiological purity: TAMC	Max. 1000 CFU/mL	$< 100 \text{ CFU/mL}$
Microbiological purity: TYMC	Max. 100 CFU/mL	$< 100 \text{ CFU/mL}$
Microbiological purity: Escherichia coli	Absence/ml	absent

Template: 1469

TAMC, TYMC and Escherichia coli are 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.

17. MRZ, 2022



Date, Signature Head of Quality Control

Batch certificate

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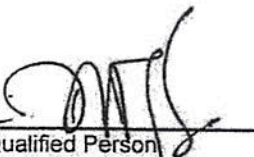
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I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the 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

Remarks:

17.02.22 
Date, Signature Qualified Person

- ☒ Dr. Hans-Jörg Lange ☐ Gudrun Prusitz ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller
- ☐ Ulrich Kontny