



aniMedica GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 21776

Product:	Suifertil 4mg/ml solution 1000ml RO	Dosage form:	Oral solution
Article number:	49330	Package size:	1000ml
Batch:	22090473 Split: 0	Marketing authorisation holder:	aniMedica GmbH
Quantity:	204 Units	Registration number:	170529
Manufacturing date:	01.09.2022	Distributor / Importer:	RO - BistriVet Rumänien
Expiry date:	31.08.2027		

Parameter	Specification	Result
Appearance	A clear, yellow solution	corresponds to
bsolute density	0,9200 ... 0,9250 g/ml	0,9204 g/ml
Refractive index	1,4700 ... 1,4800	1,4754
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	4,0 mg/ml
Assay: butylhydroxyanisole	Max. 0,077 mg/ml	0,059 mg/ml
Assay: butylhydroxytoluene	Max. 0,077 mg/ml	0,070 mg/ml
Any known impurity, single	Max. 1,0 %	0,0 %
Any unknown impurity, single	Max. 1,0 %	$< 0,1 \%$
Total impurities	Max. 3 %	$< 1 \%$

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.

08 FEB. 2023

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 7210
Geschäftsführer:
Dr. Enno Gottschalk

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www.livisto.com

Along with you



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Batch certificate

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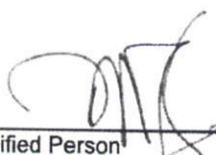
I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing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

Four horizontal lines for handwritten remarks, each with a diagonal slash through it.

12.07.2022 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange ☐ Stephan Bruns ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller ☐ Ulrich Kontny

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