



LIVISTO

aniMedica GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 19839

Product:	Suifertil 4mg/ml solution 1000ml RO		
Article number:	49330	Dosage form:	Oral solution
Batch:	22040204 Split: 0	Package size:	1000ml
Quantity:	102 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.04.2022	Registration number:	170529
Expiry date:	31.03.2027	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	A clear, yellow solution	complies
Absolute density	0,9200 ... 0,9250 g/ml	0,9202 g/ml
Refractive index	1,4700 ... 1,4800	1,4752
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	0,059 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 %	$< 1 \%$
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.

14. JUNI 2022

Date, Signature Head of Quality Control

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

Im Südfeld 9
48308 Senden-Bösensell
Deutschland

T +49 2536 33 02-0
F +49 2536 33 02-110

www.livisto.com

Along with you



aniMedica GmbH
a LIVISTO company

Batch certificate

Certificate No.: 19839

Product:	Suifertil 4mg/ml solution 1000ml RO		
Article number:	49330	Dosage form:	Oral solution
Batch:	22040204 Split: 0	Package size:	1000ml
Quantity:	102 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.04.2022	Registration number:	170529
Expiry date:	31.03.2027	Distributor / Importer:	RO - BistriVet Rumänien

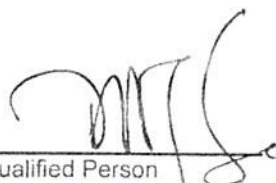
I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing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

14.06.2022 
Date, Signature Qualified Person

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

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

Im Südfeld 9
48308 Senden-Bösensell
Deutschland

T +49 2536 33 02-0
F +49 2536 33 02-110

www.livisto.com

Along with you