

**LIVISTO**aniMedica GmbH
a LIVISTO company**Certificate of Analysis**

Certificate No.: 16019

Product: Suifertil 4mg/ml solution 1000ml RO
Article number: 49330 Dosage form: Oral solution
Batch: 21020137 Split: 0 Package size: 1000ml
Quantity: 100 Units Marketing authorisation holder: aniMedica GmbH
Manufacturing date: 01.02.2021 Registration number: 170529
Expiry date: 31.01.2026 Distributor / Importer: RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	clear, yellow solution	clear, yellow solution
Density (20°C)	0,9200 ... 0,9250 g/ml	0,9206 g/ml
Refraction index	1,4700 ... 1,4800	1,4758
Net fill volume >100,0%	Min. 98 %	> 98 %
Net fill volume <98,5%	Max. 2 %	< 2 %
Net fill volume <97%	Max. 0 %	0 %
Identity Altrenogest	Retention time of sample peak has to comply with reference peak	Corresponds to
Identity Butylhydroxyanisole	Retention time of sample peak has to comply with reference peak	Corresponds to
Identity Butylhydroxytoluene	Retention time of sample peak has to comply with reference peak	Corresponds to
Assay Altrenogest	3,8 ... 4,2 mg/ml	4,0 mg/ml
Assay Butylhydroxyanisole	Max. 0,077 mg/ml	0,063 mg/ml
Assay Butylhydroxytoluene	Max. 0,077 mg/ml	0,068 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: 745

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

22. APR. 2021

Date, Signature Head of Quality Control



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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:

22.04.21 

Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange ☐ Gudrun Prußeit

☐ Dr. Jürgen Schlüter

☐