

Certificate of Analysis

Certificate No.: 25707

Product:	Suifertil 4mg/ml solution 1000ml RO		
Article number:	49330	Dosage form:	Oral solution
Batch:	24060358 Split: 0	Package size:	1000ml
Quantity:	710 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	03.06.2024	Registration number:	170529
Expiry date:	31.05.2029	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	A clear, yellow solution	A clear, yellow solution
Absolute density	0,9200 ... 0,9250 g/ml	0,9206 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	4,0 mg/ml
Assay: butylhydroxyanisole	Max. 0,077 mg/ml	0,066 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 %	0,4 %
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.

24 JUL 2024
Date, Signature Head of Quality Control