

Certificate of Analysis

Certificate No.: 22962

Product:	Suifertil 4mg/ml solution 1000ml HU		
Article number:	49325	Dosage form:	Oral solution
Batch:	23030120 Split: 0	Package size:	1000ml
Quantity:	988 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.03.2023	Registration number:	3398/1/13 NEBIH ATI
Expiry date:	28.02.2028	Distributor / Importer:	HU - Dunavet

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	1,4758
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	0,068 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: 1464

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.

27. JULI 2023

Date, Signature Head of Quality Control