

Certificate of Analysis

Certificate No.: 7579

Product: Suifertil 4mg/ml solution 1000ml RO Manufacturing date: 08-09-18
Product-No.: 49330 Expiry date: 31-08-23
Batch-No.: 18090832
Split: 0
Quantity: 100 Unit(s)

Parameter	Specification	Result
Appearance	clear, yellow solution	clear, yellow solution
Density (20°C)	0,9200 ... 0,9250 g/ml	0,9208 g/ml
Refraction index	1,4700 ... 1,4800	1,4772
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	4,1 mg/ml
Assay Butylhydroxyanisole	Max. 0,077 mg/ml	0,060 mg/ml
Assay Butylhydroxytoluene	Max. 0,077 mg/ml	0,070 mg/ml
Any known impurity, single	Max. 1,0 %	< 1,0 %
Any unknown impurity, single	Max. 1,0 %	< 1,0 %
Total impurities	Max. 3 %	< 1 %
Microbiological purity - TAMC	Max. 1000 KBE/ml	< 100 KBE/ml
Microbiological purity - TYMC	Max. 100 KBE/ml	< 100 KBE/ml
Microbiological purity - Escherichia coli	Absent/ml	absent

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

Hereby it is confirmed for the named batch, that the above information is authentic and accurate. The batch was manufactured and tested in accordance to the GMP requirements and the current authorized procedures for manufacturing and testing.

During the manufacture and testing

- ☒ no deviations/irregularities have been observed.
- ☐ the following deviations/irregularities have been observed.

These deviations/irregularities do not affect the quality of the product, because

The named batch has the required quality and is released

- ☐ for dispatch
- ☒ for the market

Comments:

23.11.18

Date, Signature Qualified Person