

Certificate of Analysis

Certificate No.: 11893

Product: Suifertil 4mg/ml solution 1000ml RO

Dosage form:

Package size: 1000ml

Product: 49330

Marketing authorisation holder:

Batch: 19050297 Split: 0

Registration number: tbd

Quantity: 98 Piece

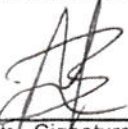
Manufacturing date: 01-05-19

Expiry date: 30-04-24

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	1,4755
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	0,063 mg/ml
Assay Butylhydroxytoluene	Max. 0,077 mg/ml	0,069 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 %

Template: 745

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

 11. MAR. 2020
Date: _____
Signature Head of Quality Control

Batch certificate

Certificate No.: 11893

Product: Suifertil 4mg/ml solution 1000ml RO

Dosage form:

Package size: 1000ml

Marketing authorisation holder:

Registration-No.: tbd

Product 49330

Batch: 19050297 Split: 0

Quantity: 98 Piece

Manufacturing 01-05-19

Expiry date: 30-04-24

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

Annotations:


Date 12/03/20
Signature Qualified Person☐ Dr. Hans-Jörg Lange☐ Gudrun Prußeit☒ Dr. Jürgen Schlüter☐