

Certificate of Analysis

Product: **Fertagyl 10x5ml 296**
Batch: **A253A01**

Country: **Russian Fed.**
Sales Order Number: **1105737541 / 10**
Delivery Number: **1207167048 / 900002**



Material Number:
109516
Type of Container: **Vial** Package Size: **5 ML**
Manufacturing Date: **19-Jan-2018** Expiry Date: **Dec-2020**
Storage Conditions:
2-8°C

CERTIFICATION BY THE MANUFACTURER

I herewith certify that the presented information is authentic and accurate. All measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended. This batch has been manufactured /fabricated (incl. APIs and intermediates if applicable) including packaging and quality control, in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Name:
Function:
Date:
Signature:

Petra Huwe
Qualified Person
04. April 2018

Dr. Susanne Jost, Qualified Person

Certificate of Analysis

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Results of Analysis

Test	Method	Specification	Result
Characters - Color	Visual Examination	Colorless	Complies
Characters - Physical State	Visual Examination	Aqueous Solution	Complies
Characters - Clarity	Visual Examination	Clear	Complies
Characters - Clarity	Ph. Eur. 2.9.20.	Free from Visible Particles	Complies
Appearance of Solution	Ph. Eur. 2.2.2.	≤ B9	Complies
Appearance of Solution	Ph. Eur. 2.2.1.	≤ Reference Suspension I	Complies
Extractable Volume	Ph. Eur. 2.9.17.	5.2 - 5.4 mL	5.4 mL
Fill Volume	Weight Measurement	≥ 5	5
Identification Benzyl Alcohol	HPLC	Rt of the Corresponding Peaks Comply	Complies
Identification Gonadorelin	HPLC	Rt of the Corresponding Peaks Comply	Complies
pH	Ph. Eur. 2.2.3	4.7 - 5.5	5.0
Assay Benzyl Alcohol	HPLC	9.5 - 10.5 mg/mL	10.0 mg/mL
Assay Gonadorelin	HPLC	0.095 - 0.105 mg/mL	0.098 mg/mL
Rel. Peptides, Single	HPLC	≤ 3 %	0 %
Rel. Peptides, Sum	HPLC	≤ 6 %	0 %
Rel. Substances, Benzaldehyde	HPLC	≤ 0.05 %	0.01 %
Sterility	Ph. Eur. 2.6.1.	No Growth Detectable	Complies
Bacterial Endotoxins	USP Test Method < 85 >, Ph. Eur. 2.6.14	≤ 500 IU / ml	Complies

Intervet International GmbH
Feldstraße 1a
85716 UNTERSCHLEISSHEIM
GERMANY



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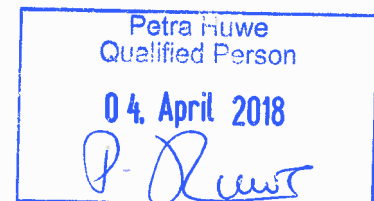
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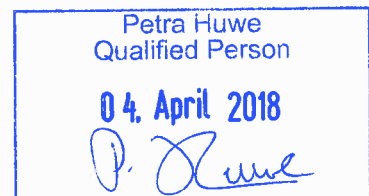
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MSD
Animal Health

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