

Certificate of Analysis

Product: **COVINAN, 20 ML**
Batch: **A034A01**



Country: **Hungary**

Sales Order Number: **1103149458 / 10**
Delivery Number: **1203966992 / 900002**
Strength: **Proligeston 100 mg/ml**
Pharmaceutical Form: **suspension for injection**

Material Number:
013114

Type of Container: **Glass vials, type I**
Package Size: **20 ML**

Manufacturing Date: **13-Mar-2014**
Expiry Date: **Feb-2017**

Storage Conditions:
Below 25°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:

S.T.M. Verstegen
Qualified Person
22 APR 2014


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Results of Analysis

<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Appearance - Color		White to off-white	White to Off-White
Appearance - Physical State		Suspension	Suspension
Filling Volume		≥ 20.0 mL/VL	20.3 mL/VL
pH	Ph. Eur. 2.2.3	5.8 - 7.7	6.8
Identity Proligestone		Positive	Positive
ID Methyl Parahydroxybenzoate		Positive	Positive
ID Propyl Parahydroxybenzoate		Positive	Positive
Content Proligestone		95 - 105 %	100 %
Content Methyl Parahydroxybenzoate		0.92 - 1.12 mg/mL	1.01 mg/mL
Content Propyl Parahydroxybenzoate		0.11 - 0.13 mg/mL	0.12 mg/mL
Any Unspecified Degr. Products > 0.3%		≤ 1.0 %area	0.0 %area
Degradation products, total		≤ 2.0 %area	0.7 %area
Resuspendability		≤ 10 Seconds	≤ 10 Seconds
Syringeability		Expellable through 23G Needle	Expellable through 23G Needle
Particle Size		95% ≤ 100 µm	Complies
Sterility		No Growth Detectable	No Growth Detectable



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