



# CERTIFICATE OF ANALYSIS

Name	<b>OVARELIN</b>	Batch N°	<b>191A8</b>
Presentation	10 ml	Manufacturing date	<b>25-SEP-2014</b>
Code list	<b>C51310D</b>	Expiry date	<b>25-SEP-2016</b>

Tests	Specifications	Results
<b>GENERAL CHARACTERISTICS</b>		
Appearance :	Clear, colourless solution, practically free from visible particles	COMPLIES
Average fill volume :	100 - 110 %	108
pH :	5.5 - 6.5	5.8
<b>IDENTIFICATIONS</b>		
Benzyl alcohol :	RT identical to standard	COMPLIES
Gonadoreline : (HPLC/UV diode array)	Rt of test substance concordant with the Rt of reference substance and UV spectra superimposable	COMPLIES
<b>ASSAYS</b>		
Benzyl alcohol :	1.35 - 1.65 g % ml	1.51
Gonadorelin (as diacetate tetrahydrate) :	47.5 - 52.5 µg/ml	51.4
<b>STERILITY</b>		
According to Ph. Eur.	Sterile	COMPLIES

This batch has been tested in reference to the dossier in force and has been found to meet the specification requirements

**COMPLIES / NOT COMPLIES**

Checked by : **Maureen MAYENC**

Batch Release number **362476**

Batch Release date **10-DEC-2014**

**ACCEPTED by**

**Stéphanie ZEBST**  
Quality Assurance Manager

The undersigned certifies this is a true copy of the results of tests and assays.

Page 1 sur 1