



CERTIFICATE OF ANALYSIS

Name **OVARELIN** Batch N° **195A2**
Presentation **10 ml**
Code list **C51310D** Manufacturing date **17-OCT-2014**
Expiry date **17-OCT-2016**

Tests	Specifications	Results
GENERAL CHARACTERISTICS		
Appearance :	Clear, colourless solution, practically free from visible particles	COMPLIES
Average fill volume :	100 - 110 %	108
pH :	5.5 - 6.5	6.1
IDENTIFICATIONS		
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
ASSAYS		
Benzyl alcohol :	1.35 - 1.65 g % ml	1.54
Gonadorelin (as diacetate tetrahydrate) :	47.5 - 52.5 µg/ml	50.1
STERILITY		
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 **362316**

Batch Release date **5-DEC-2014**

ACCEPTED by

Stéphanie ZEBST
Quality Assurance Manager

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