



## CERTIFICATE OF ANALYSIS

Name	ALTRESYN	Batch N°	111A2
Presentation	540 ml vial	Manufacturing date	21-OCT-2014
Code list	C56040B	Expiry date	21-OCT-2017

Tests	Specifications	Results
<b>GENERAL CHARACTERISTICS</b>		
Appearance :	Clear yellow solution	COMPLIES
Relative density :	0.900 - 0.940	0.923
Average fill volume :	100 - 110 %	100
Water content :	<0.10 %	0.02
<b>IDENTIFICATIONS</b>		
Altrenogest : (HPLC/UV diode array)	Rt of test substance concordant with the Rt of reference substance and UV spectra superimposable	COMPLIES
Butylhydroxyanisole : (GC)	RT identical to standard	COMPLIES
Butylhydroxytoluene : (GC)	RT identical to standard	COMPLIES
<b>ASSAYS</b>		
Altrenogest :	0.380 - 0.420 g % ml	0.402
Butylhydroxyanisole :	6.3 - 7.7 mg/100ml	7.0
Butylhydroxytoluene :	6.3 - 7.7 mg/100ml	7.2
Microbial contamination :	Test performed on one batch every ten	
*Total viable aerobic count:		
- Bacteria	<= 1000 UFC/ml	NA
- Fungi	<= 100 UFC/ml	NA

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 : Cath. GOOSSAERT

Batch Release number 361142

Batch Release date 19-NOV-2014

ACCEPTED by

Olivier DENIAU  
Qualified Person

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

Page 1 sur 2



CERTIFICATE OF ANALYSIS

Name **ALTRESYN** Batch N° **111A2**  
Presentation **540 ml vial**  
Code list **C56040B** Manufacturing date **21-OCT-2014**  
Expiry date **21-OCT-2017**

Tests	Specifications	Results
<b>ASSAYS</b>		
*Escherichia Coli	Absence in 1 ml	NA

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 : Cath. GOOSSAERT

Batch Release number 361142

Batch Release date **19-NOV-2014**

ACCEPTED by

Olivier DENIAU  
Qualified Person

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