



## CERTIFICATE OF ANALYSIS

Name	<b>ALTRESYN</b>	Batch N°	<b>92A1</b>
Presentation	1080 ml vial	Manufacturing date	10-MAR-2014
Code list	<b>C56030D</b>	Expiry date	10-MAR-2017

Tests	Specifications	Results
<b>GENERAL CHARACTERISTICS</b>		
Appearance :	Clear yellow solution	COMPLIES
Relative density :	0.900 - 0.940	0.922
Average fill volume :	100 - 110 %	101
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	6.9
Butylhydroxytoluene :	6.3 - 7.7 mg/100ml	6.5
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 348449

Batch Release date **9-APR-2014**

ACCEPTED by  Valérie AUGELLO  
Qualified Person

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



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Code list **C56030D** Manufacturing date 10-MAR-2014  
Expiry date 10-MAR-2017

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

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**COMPLIES / NOT COMPLIES**

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