



## CERTIFICATE OF ANALYSIS

Name **ALTRESYN**  
Presentation **1080 ml vial**  
Code list **C56030D**

Batch N° **90A1**  
Manufacturing date **24-JAN-2014**  
Expiry date **24-JAN-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 %	101
Water content :	<0.10 %	0.03
<b>IDENTIFICATIONS</b>		
Altrenogest : (HPLC/UV diode array)	Rt of test substance concordant with the Rt of reference substance and UV spectra superimposable	COMPLIES
Buthydroxyanisole : (GC)	RT identical to standard	COMPLIES
Buthydroxytoluene : (GC)	RT identical to standard	COMPLIES
<b>ASSAYS</b>		
Altrenogest :	0.380 - 0.420 g % ml	0.403
Buthydroxyanisole :	6.3 - 7.7 mg/100ml	7.2
Buthydroxytoluene :	6.3 - 7.7 mg/100ml	7.1
Microbial contamination :	Test performed on one batch every ten	
*Total viable aerobic count:		
Bacteria	<= 1000 UFC/ml	COMPLIES
Fungi	<= 100 UFC/ml	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  
Batch Release number **345422** Checked by: **Catherine WADE**  
Batch Release date **21-FEB-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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