



CERTIFICATE OF ANALYSIS

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

Batch N° **99A1**
Manufacturing date 18-JUN-2014
Expiry date 18-JUN-2017

Tests	Specifications	Results
GENERAL CHARACTERISTICS		
Appearance :	Clear yellow solution	COMPLIES
Relative density :	0.900 - 0.940	0.922
Average fill volume :	100 - 110 %	101
Water content :	<0.10 %	0.01
IDENTIFICATIONS		
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
ASSAYS		
Altrenogest :	0.380 - 0.420 g % ml	0.404
Butylhydroxyanisole :	6.3 - 7.7 mg/100ml	6.6
Butylhydroxytoluene :	6.3 - 7.7 mg/100ml	6.9
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 : Catherine WADE

Batch Release number 353656

Batch Release date **7-JUL-2014**

ACCEPTED by

Laurent MAGNIES
Qualified Person

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



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ASSAYS		
*Escherichia Coli	Absence in 1 ml	NA

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