



CERTIFICATE OF ANALYSIS

Name	ALTRESYN	Batch N°	108A1
Presentation	1080 ml vial	Manufacturing date	25-SEP-2014
Code list	C56030D	Expiry date	25-SEP-2017

Tests	Specifications	Results
GENERAL CHARACTERISTICS		
Appearance :	Clear yellow solution	COMPLIES
Relative density :	0.900 - 0.940	0.919
Average fill volume :	100 - 110 %	101
Water content :	<0.10 %	0.02
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	0.400
Butylhydroxyanisole :	6.3 - 7.7 mg/100ml	6.8
Butylhydroxytoluene :	6.3 - 7.7 mg/100ml	7.4
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 : L-A LE MARCHAND

Batch Release number 359670

Batch Release date **22-OCT-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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Name **ALTRESYN** Batch N° **108A1**
Presentation **1080 ml vial**
Code list **C56030D** Manufacturing date **25-SEP-2014**
Expiry date **25-SEP-2017**

Tests	Specifications	Results
ASSAYS		
*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 : **L-A LE MARCHAND**

Batch Release number **359670**

Batch Release date **22-OCT-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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