



CERTIFICATE OF ANALYSIS

Name	ALTRESYN	Batch N°	113A1
Presentation	1080 ml vial	Manufacturing date	20-NOV-2014
Code list	C56030D	Expiry date	20-NOV-2017

Tests	Specifications	Results
GENERAL CHARACTERISTICS		
Appearance :	Clear yellow solution	COMPLIES
Relative density :	0.900 - 0.940	0.921
Average fill volume :	100 - 110 %	102
Water content :	<0.10 %	0.03
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	0.401
Butylhydroxyanisole :	6.3 - 7.7 mg/100ml	7.2
Butylhydroxytoluene :	6.3 - 7.7 mg/100ml	7.5
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 362491

Batch Release date **9-DEC-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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