



CERTIFICATE OF ANALYSIS

Name **ALTRESYN**
Presentation **540 ml vial**
Code list **C56040B**

Batch N° **100A1**
Manufacturing date **16-JUN-2014**
Expiry date **16-JUN-2017**

Tests	Specifications	Results
GENERAL CHARACTERISTICS		
Appearance :	Clear yellow solution	COMPLIES
Relative density :	0.900 - 0.940	0.921
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	0.404
Butylhydroxyanisole :	6.3 - 7.7 mg/100ml	6.8
Butylhydroxytoluene :	6.3 - 7.7 mg/100ml	7.0
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~~

Checked by : Cath. GOOSSAERT

Batch Release number 353685

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.

Page 1 sur 2



CERTIFICATE OF ANALYSIS

Name ALTRESYN Batch N° 100A1
Presentation 540 ml vial
Code list C56040B
Manufacturing date 16-JUN-2014
Expiry date 16-JUN-2017

Tests	Specifications	Results
ASSAYS		
*Escherichia Coli	Absence in 1 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

Checked by : Cath. GOOSSAERT

Batch Release number 353685

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.

Page 2 sur 2