



## CERTIFICATE OF ANALYSIS

Name	<b>PRID DELTA</b>	Batch N°	<b>30C11</b>
Presentation	1 box of 10 devices	Manufacturing date	10-FEB-2015
Code list	<b>C61410A</b>	Expiry date	10-FEB-2018

Tests	Specifications	Results
<b>CHARACTERS</b>		
Appearance :	Whitish triangular device with a double 50 cm cord attached	COMPLIES
Average mass :		
- total device	22.80 - 25.20 g	23.83
- over-moulding	13.30 - 14.70 g	13.88
Uniformity of dosage units :	Complies to Ph.Eur. 2.9.40	COMPLIES
Dissolution test :		
% of progesterone dissolved in 3 hours	15 - 35	21
% of progesterone dissolved in 48 hours	40 - 60	46
% of progesterone dissolved in 168 hours	>60	70
<b>IDENTIFICATIONS</b>		
Progesterone: (HPLC/ UV diode array)	Rt of test substance concordant with the Rt of reference substance and UV spectra superimposable	COMPLIES
<b>ASSAYS</b>		
Progesterone :	1.47 - 1.63 g/ device	1.55
<b>MICROBIOLOGY</b>		
Microbial contamination :	Test performed on one batch every ten	

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 372637

Batch Release date **25-MAY-2015**

**ACCEPTED by**

Nathalie LEFEUVRE  
Qualified Person

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

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Tests	Specifications	Results
<b>MICROBIOLOGY</b>		
Total viable aerobic count :	<100 UFC/g	NA
Total combined Yeasts/ Moulds count	<10 UFC/g	NA
Pseudomonas aeruginosa :	Absence in 1 g	NA
Staphylococcus aureus :	Absence in 1 g	NA
Candida albicans :	Absence in 1 g	NA

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