



CERTIFICATE OF ANALYSIS

Name	PRID DELTA	Batch N°	29I11
Presentation	1 box of 10 devices	Manufacturing date	21-JAN-2015
Code list	C61410A	Expiry date	21-JAN-2018

Tests	Specifications	Results
CHARACTERS		
Appearance :	Whitish triangular device with a double 50 cm cord attached	COMPLIES
Average mass :		
- total device	22.80 - 25.20 g	23.87
- over-moulding	13.30 - 14.70 g	14.01
Uniformity of dosage units :	Complies to Ph.Eur. 2.9.40	COMPLIES
Dissolution test :		
% of progesterone dissolved in 3 hours	15 - 35	20
% of progesterone dissolved in 48 hours	40 - 60	45
% of progesterone dissolved in 168 hours	>60	69
IDENTIFICATIONS		
Progesterone: (HPLC/ UV diode array)	Rt of test substance concordant with the Rt of reference substance and UV spectra superimposable	COMPLIES
ASSAYS		
Progesterone :	1.47 - 1.63 g/ device	1.59
MICROBIOLOGY		
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 371187

Batch Release date **30-APR-2015**

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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Code list **C61410A** Manufacturing date 21-JAN-2015
Expiry date 21-JAN-2018

Tests	Specifications	Results
MICROBIOLOGY		
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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