



# Certificate of Analysis

PFIZER MANUFACTURING BELGIUM NV  
RIJKSWEG 12  
B-2870 PUURS (BELGIUM)  
TEL: +32 (0)3 890.92.11  
FAX: +32 (0)3 889.65.32

Page 1 of 1

Puurs Lot Number: A01841

Date Generated: 03-2013

Product Name: DEPO-PROMONE SAS 50MG/ML  
1X5ML V (MEDROXYPROGESTERONE ACETATE)

Item Number: 3039204025

Date of Manufacture: 11-2012

Expiration Date: 10-2017

Specification Name: P0392001003EU

TEST	RESULT	UNIT	LIMITS
DESCRIPTION	MEETS TEST		WHITE SUSPENSION: MEETS TEST
EXTRACTABLE VOLUME	MEETS TEST		MEETS PH EUR REQUIREMENTS
IDENTIFICATION MEDROXYPROGESTERONE ACETATE	POSITIVE		POSITIVE
IDENTIFICATION METHYLPARABEN	POSITIVE		POSITIVE
IDENTIFICATION PROPYLPARABEN	POSITIVE		POSITIVE
MEDROXYPROGESTERONE ACETATE	50.3	MG/ML	47.5 TO 52.5 MG/ML
METHYLPARABEN	1.27	MG/ML	0.84 TO 1.43 MG/ML
PARTICLE SIZE LT 10 MCM	MEETS TEST		75 % LT 10 MICRONS
PARTICLE SIZE LT 20 MCM	MEETS TEST		99 % LT 20 MICRONS
PH	6.3		3.0 TO 7.0
PROPYLPARABEN	0.134	MG/ML	0.070 TO 0.154 MG/ML
STERILITY	MEETS TEST		MEETS PH EUR REQUIREMENTS

BATCH: Z07567

I HEREBY CERTIFY THAT THE ABOVE INFORMATION IS AUTHENTIC AND ACCURATE.  
THIS BATCH OF PRODUCT HAS BEEN FABRICATED/MANUFACTURED, INCLUDING PACKAGING AND QUALITY CONTROL IN FULL COMPLIANCE WITH THE GMP REQUIREMENTS OF THE LOCAL REGULATORY AUTHORITY AND WITH THE SPECIFICATIONS IN THE MARKETING AUTHORISATION OF THE IMPORTING COUNTRY:

HUNGARY - HU

THE BATCH PROCESSING/PACKAGING AND ANALYSIS WERE  
REVIEWED AND FOUND TO BE IN COMPLIANCE WITH GMP.

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Electronic Signature: Ilse De Keuster Lot Release Local Timestamp: 29-MAR-2013 11:57:51 Server Timestamp: 29-MAR-2013 11:57:46

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.

Diszpó: PN-ZA13000691 Vevő: PRIMA VET  
Szállító: Zoetis Hungary Kft.  
Az eredetiről készült hiteles másolat.

Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

File név: PN00007396 Egyedi sorszám: PN0000068772 1 másolat  
Oldal/Lap 1 / 1 Anyaglap: PN0127/13

Nyomtatás dátuma: 2013.07.24

**CertEx v3.01e**