

PFIZER MANUFACTURING BELGIUM NV RIJKSWEG 12 2870 PUURS (BELGIUM)

TEL: +32 (0)3 890.92.11 FAX: +32 (0)3 889.65.32

Puurs Batch Number: GM3314

Product Name: DEPO-PROVERA SAS 150 MG/ML

25X1ML VIAL (MEDROXYPROGESTERONE ACETATE)

Material Number: F000049351 Date of Manufacture: 09-2022

Expiration Date:08-2026

Date Generated: 07-2023

Specification Name: P0740003003USP

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TEST	RESULT	UNIT	LIMITS
ASSAY MEDROXYPROGESTERONE ACETATE	153	MG/ML	135 TO 165 MG/ML (90.0 % TO 110.0 % OF LABEL CLAIM)
UNIFORMITY OF DOSAGE UNITS BY CONTENT UNIFORMITY	MEETS TEST		MEETS USP REQUIREMENTS
DESCRIPTION	MEETS TEST		WHITE SUSPENSION
BACTERIAL ENDOTOXINS	MEETS TEST		NOT MORE THAN 2.3 EU/MG AT RELEASE
EXTRACTABLE VOLUME IDENTIFICATION MEDROXYPROGESTERONE ACETATE (IR)	MEETS TEST POSITIVE		MEETS USP REQUIREMENTS POSITIVE
IDENTIFICATION MEDROXYPROGESTERONE ACETATE (HPLC)	POSITIVE		POSITIVE: THE RETENTION TIME OF THE SAMPLE CORRESPONDS TO REFERENCE
LARGEST UNSPECIFIED DEGRADANT	0.2	%	NOT MORE THAN 0.2 %
MEDROXYPROGESTERONE PARTICLE SIZE LESS THAN 10 MICRONS	0.2 MEETS TEST	%	NOT MORE THAN 0.7 % NOT LESS THAN 75 %
PARTICLE SIZE LESS THAN 20 MICRONS	MEETS TEST		NOT LESS THAN 99 %
PH STERILITY	6.2 MEETS TEST		3.0 TO 7.0 MEETS USP REQUIREMENTS
TOTAL DEGRADATION PRODUCTS	0.3	%	NOT MORE THAN 0.7 %

BATCH: GL0339



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Page 2 of 2

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:

DONORBUSINESS - DB

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

THIS SHIPMENT AND COA ARE FOR UNFPA DONOR BUSINESS - Peru - PO 70002377.

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

Electronic Signature: Karen Coppens Lot Release Local Timestamp: 20-JUL-2023 07:30:50 Server Timestamp: 20-JUL-2023 07:30:34

Signature QP delegate

Sebastiaan Dhalnens

Sebastiaan Dhaenens

20 Jul 2023 08:04:048-0400

REASON: I approve this document.

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TEL: +32 (0)3 890.92.11 FAX: +32 (0)3 889.65.32

Puurs Batch Number: GM3303

Product Name: DEPO-PROVERA SAS 150 MG/ML

25X1ML VIAL (MEDROXYPROGESTERONE ACETATE)
Material Number: F000049351
Date of Manufacture: 09-2022

Date of Manufacture: 09-2022 Expiration Date: 08-2026 Date Generated: 06-2023

Specification Name: P0740003003USP

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TEST	RESULT	UNIT	LIMITS
ASSAY MEDROXYPROGESTERONE ACETATE	157	MG/ML	135 TO 165 MG/ML (90.0 % TO 110.0 % OF LABEL CLAIM)
UNIFORMITY OF DOSAGE UNITS BY CONTENT UNIFORMITY	MEETS TEST		MEETS USP REQUIREMENTS
DESCRIPTION	MEETS TEST		WHITE SUSPENSION
BACTERIAL ENDOTOXINS	MEETS TEST		NOT MORE THAN 2.3 EU/MG AT RELEASE
EXTRACTABLE VOLUME IDENTIFICATION MEDROXYPROGESTERONE ACETATE (IR)	MEETS TEST POSITIVE		MEETS USP REQUIREMENTS POSITIVE
IDENTIFICATION MEDROXYPROGESTERONE ACETATE (HPLC)	POSITIVE		POSITIVE: THE RETENTION TIME OF THE SAMPLE CORRESPONDS TO REFERENCE
LARGEST UNSPECIFIED DEGRADANT	0.2	%	NOT MORE THAN 0.2 %
MEDROXYPROGESTERONE PARTICLE SIZE LESS THAN 10 MICRONS	0.2 MEETS TEST	%	NOT MORE THAN 0.7 % NOT LESS THAN 75 %
PARTICLE SIZE LESS THAN 20 MICRONS	MEETS TEST		NOT LESS THAN 99 %
PH STERILITY	6.7 MEETS TEST		3.0 TO 7.0 MEETS USP REQUIREMENTS
TOTAL DEGRADATION PRODUCTS	0.3	%	NOT MORE THAN 0.7 %

BATCH: GL0338



PFIZER MANUFACTURING BELGIUM NV RIJKSWEG 12 2870 PUURS (BELGIUM)

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Puurs Batch Number: GM3303

Product Name: DEPO-PROVERA SAS 150 MG/ML 25X1ML VIAL (MEDROXYPROGESTERONE ACETATE)

Material Number: F000049351 Date of Manufacture: 09-2022 Expiration Date:08-2026 Date Generated: 06-2023

Specification Name: P0740003003USP

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Electronic Signature: MARIE LAMBLIN Lot Release Local Timestamp: 06-JUN-2023 14:13:43 Server Timestamp: 06-JUN-2023 14:12:58

Signature QP Delegate

Liselotte Bal Liselotte Bal 07 Jun 2023 03:06:045-0400

REASON: I approve this document.

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