

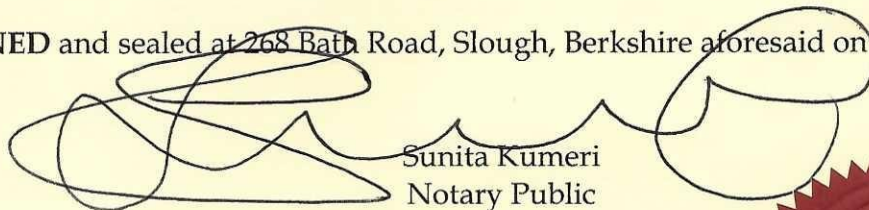


BE IT KNOWN that I, Sunita Kumeri of, 268 Bath Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

CERTIFY that

1. The signature set and subscribed to the certificate at the foot of the first page of the copy document annexed hereto is genuine having been subscribed thereto by Zoe Bruce whose identity I the Notary attest and who is duly authorised by Pfizer Limited ("the Company") to represent them in this matter, and
2. Zoe Bruce has thereby certified on behalf of the company that the Certificate of GMP Compliance of a Manufacturer issued to Valdepharm annexed hereto is a true copy of the original document.

SIGNED and sealed at 268 Bath Road, Slough, Berkshire aforesaid on 29th May 2020.


Sunita Kumeri
Notary Public
England and Wales



Protocol No. 2120



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country: United Kingdom of Great Britain and Northern Ireland

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Has been signed by

Sunita Kumeri

Acting in the capacity of

Notary Public

Bears the seal / stamp of

The Said Notary Public

Certified

Attesté / Certificado

at London 6. the 01 June 2020

by Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs

Number APO-1915003

Seal / stamp

Sceau / timbre
Sello / timbre



10. Signature S. Swift

Signature
Firma

[Signature]

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French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER : 19MPP018HFR01

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ^{(1), (2)}

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of France confirms the following:

The manufacturer : **VALDEPHARM**

Site address **PARC INDUSTRIEL D'INCARVILLE, PARC DE LA FRINGALE, CS 10806, VAL DE REUIL (Cedex), 27106, France**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-01-24**, it is considered that it complies with :

- The principles of GMP for active substances ⁽³⁾ referred to in Article 47 of Directive 2001/83/EC

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

⁽¹⁾ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

⁽²⁾ Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

⁽³⁾ These requirements fulfil the GMP recommendations of WHO.

Part 2

Manufacture of active substance. Names of substances subject to inspection :

[840] BICALUTAMIDE (en)
[841] ESTRADIOL BENZOATE (en)
[898] ESTRADIOL VALERATE (en)
[842] ESTRAMUSTINE DISODIUM PHOSPHATE MONOHYDRATE (en)
[338] HYDROCORTISONE HYDROGEN SUCCINATE (en)
[843] IBUPROFEN (en)
[1673] NORETHISTERONE (en)
[1674] NORETHISTERONE ACETATE (en)
[1672] SODIUM ISOSPAGLUMATE (en)
[200] CHLORMADINONE ACETATE (en)
[285] ESTRADIOL HEMIHYDRATE (en)
[655] MEDROXYPROGESTERONE ACETATE (en)
[421] METHYLPREDNISOLONE HYDROGEN SUCCINATE (en)
[456] NOMEGESTROL ACETATE (en)
BENZALKONIUM BROMIDE (en)
CLOTIAPINE (en)
TRAZODONE HYDROCHLORIDE (en)
[497] TIXOCORTOL PIVALATE (en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : BICALUTAMIDE

3.5 General Finishing Steps

- 3.5.1 Physical processing steps :
Micronisation
- 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
- 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

Active Substance : ESTRADIOL BENZOATE

3.1 Manufacture of Active Substance by Chemical Synthesis

	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : -
3.5	General Finishing Steps
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : ESTRADIOL VALERATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Recrystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Micronisation 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : ESTRAMUSTINE DISODIUM PHOSPHATE MONOHYDRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : -
3.5	General Finishing Steps
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : HYDROCORTISONE HYDROGEN SUCCINATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Recrystallisation
3.5	General Finishing Steps
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : IBUPROFEN	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps : Recrystallisation
3.5	General Finishing Steps
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Active Substance : NORETHISTERONE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Recrystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Micronisation 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : NORETHISTERONE ACETATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Recrystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Micronisation 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : SODIUM ISOSPAGLUMATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
3.5	General Finishing Steps
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : CHLORMADINONE ACETATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Recrystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Micronisation 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : ESTRADIOL HEMIHYDRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Recrystallisation
3.5	General Finishing Steps

3.5.1	Physical processing steps : Micronisation
3.5.2	Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.5.3	Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
3.6.1	Physical / Chemical testing
3.6.2	Microbiological testing excluding sterility testing
Active Substance : MEDROXYPROGESTERONE ACETATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
3.1.1	Manufacture of active substance intermediates
3.1.2	Manufacture of crude active substance
3.1.3	Salt formation / Purification steps : Recrystallisation
3.5	General Finishing Steps
3.5.1	Physical processing steps : Micronisation
3.5.2	Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.5.3	Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
3.6.1	Physical / Chemical testing
3.6.2	Microbiological testing excluding sterility testing
Active Substance : METHYLPREDNISOLONE HYDROGEN SUCCINATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
3.1.1	Manufacture of active substance intermediates
3.1.2	Manufacture of crude active substance
3.1.3	Salt formation / Purification steps : -
3.5	General Finishing Steps
3.5.2	Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.5.3	Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
3.6.1	Physical / Chemical testing
3.6.2	Microbiological testing excluding sterility testing
Active Substance : NOMEGESTROL ACETATE	
3.5	General Finishing Steps
3.5.1	Physical processing steps : Micronisation
3.5.2	Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.5.3	Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
Active Substance : BENZALKONIUM BROMIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis
3.1.2	Manufacture of crude active substance
3.5	General Finishing Steps
3.5.2	Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	Quality Control Testing
3.6.1	Physical / Chemical testing
Active Substance : CLOTIAPINE	
3.1	Manufacture of Active Substance by Chemical Synthesis
3.1.2	Manufacture of crude active substance
3.1.3	Salt formation / Purification steps : Recrystallisation
3.5	General Finishing Steps
3.5.2	Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.5.3	Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
3.6.1	Physical / Chemical testing

	3.6.2 Microbiological testing excluding sterility testing
Active Substance : TRAZODONE HYDROCHLORIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : -
3.5	General Finishing Steps
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance : TIXOCORTOL PIVALATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : -
3.5	General Finishing Steps
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users) :

Estradiol hemihydrate is synthesised from estrone / Sodium isopaglumate is also known as naega salt / Ethinylestradiol is micronised by a contract manufacturer / Signatory : Mrs Linda Gallais, head of starting materials inspection department — The ANSM does not issue hard copies of good practices certificates

2019-05-15

Name and signature of the authorised person of the Competent Authority of France

Confidential

French National Agency for Medicines and Health Products Safety

Tel : **Confidential**

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Contents: Documents -
general business



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Nikita Harika

From: Pardo, Kelly <Kelly.Pardo@pfizer.com>
Sent: 15 January 2021 13:52
To: Kelly Wells; Brian Howes; Nikita Harika
Subject: CST-51518-97354-GMP-Kalamazoo-MEDROXYPROGESTERONE ACETATE-Chile-Tenders-Legalization in UK
Attachments: Pharmacia & Upjohn Kalamazoo GMP-ML 2021.pdf

Categories: Requets

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All required details are below:

Recipient Country	Document Type (CPP, GMP etc)	Business Unit	PO Charge Code	Product Name	Authentication Required	Country of Authentication	Date Required by	Pfizer Ref No (please quote on invoice)
Chile	GMP	PBG	8502139983	MEDROXYPROGESTERONE ACETATE	Apostille	UK	12-Feb-2021	51518-97354

When the document are dispatched, please send a PDF copy to kelly.pardo@pfizer.com recipient details identified above, including the tracking details.
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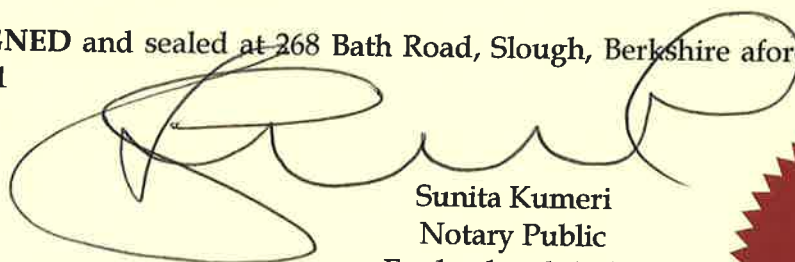


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CERTIFY that

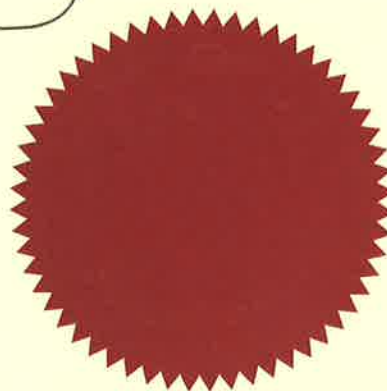
1. The signature set and subscribed to the certificate at the foot of the first page of the copy document annexed hereto is genuine having been subscribed thereto by Zoe Bruce whose identity I the Notary attest and who is duly authorised by Pfizer Limited ("the Company") to represent them in this matter, and Zoe Bruce has thereby certified on behalf of the company that the Affidavit of Good Manufacturing Practices annexed hereto is a certified true copy of the original document.

SIGNED and sealed at 268 Bath Road, Slough, Berkshire aforesaid on 18th January 2021



Sunita Kumeri
Notary Public
England and Wales

Protocol No. 15/21



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. **Country:** United Kingdom of Great Britain and Northern Ireland
Pays / País:

This public document

Le présent acte public / El presente documento público

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a été signé par Sunita Kumeri
ha sido firmado por

3. **Acting in the capacity of**
agissant en qualité de Notary Public
quien actúa en calidad de

4. **Bears the seal / stamp of**
est revêtu du sceau / timbre de The Said Notary Public
y está revestido del sello / timbre de

Certified

Attesté / Certificado

5. **at** London
à / en

6. **the** 19 January 2021
le / el día

7. **by** Her Majesty's Principal Secretary of State for
par / por Foreign, Commonwealth and Development Affairs

8. **Number** APO-2202537
sous no / bajo el numero

9. **Seal / stamp**
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10. **Signature** R. James
Signature
Firma

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Pfizer Inc

500 Arcola Road
Collegeville, PA 19426
Tel 484-865-3683
Fax 484-865-4301

Email: siobhan.carmody@pfizer.com

Siobhan Carmody

Vice President
Pfizer Global Supply
Quality Systems and Compliance

***Affidavit
of
Good Manufacturing Practices***

State of Pennsylvania

County of Montgomery

Siobhan Carmody, Vice President, Quality Systems and Compliance, Pfizer Inc, being duly sworn, certifies that Pharmacia & Upjohn Company LLC, a subsidiary of Pfizer Inc., located at 7000 Portage Road, Kalamazoo, Michigan (MI) 49001, United States (USA), is registered with the Food and Drug Administration (FDA). A copy of the current FDA Drug Establishment Registration with registration number 1810189 is attached for your reference. Further, this manufacturing site is registered with the FDA in accordance with US Federal Regulation 21 CFR Subpart C and Subpart D.

The regulation can be accessed at:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

The US FDA Drug Establishments Current Registration Site can be accessed at:

<https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site>

The manufacturing facility is subject to periodic inspections by FDA. The latest inspection, completed November 2018 showed that the plant, at that time, was in substantial compliance with the current Good Manufacturing Practices (GMP) regulations set out by Title 21 CFR §210-211, as required by the Federal Food, Drug and Cosmetic Act and as recommended by the World Health Organization.

DocuSigned by:

Siobhan Carmody

December 14, 2020

5DCC5994280748B...

Siobhan Carmody

I, Zoe Bruce, on behalf of Pfizer
certify this document
to be a true copy
of the original

Establishments Current Registration

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Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
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