*Agenzia Italiana del Farmaco*

CERTIFICATE NUMBER: ***IT/100/H/2020***

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

## Part 1

Issued following an inspection in accordance with :

The competent authority of Italy confirms the following:
The manufacturer: ***PATHEON ITALIA S.P.A.***
Site address: ***VIALE G.B. STUCCHI, 110, MONZA (MB), 20900, Italy***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***aM79/2020*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-05-29***, it is considered that it complies with:

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.*

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## Part 2

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| **1 MANUFACTURING OPERATIONS** | |
| **1.1** | **Sterile products** |
| | *1.1.1 Aseptically prepared (processing operations for the following dosage forms)*<br>1.1.1.2 Lyophilisates<br>Special Requirements<br>7 Other: Prostaglandins(en)<br>1.1.1.4 Small volume liquids<br>Special Requirements<br>7 Other: Immunosuppressive(en) |
| | *1.1.2 Terminally Sterilised (processing operations for the following dosage forms)*<br>1.1.2.3 Small volume liquids |
| | *1.1.3 Batch certification* |
| **1.2** | **Non-sterile products** |
| | *1.2.1 Non-sterile products (processing operations for the following dosage forms)*<br>1.2.1.1 Capsules, hard shell<br>1.2.1.8 Other solid dosage forms: Powders and Granules(en)<br>1.2.1.13 Tablets |
| | *1.2.2 Batch certification* |
| **1.3** | **Biological medicinal products (list of product types)** |
| | *1.3.1 Biological medicinal products (list of product types)*<br>1.3.1.2 Immunological products<br>1.3.1.5 Biotechnology products |
| **1.5** | **Packaging** |
| | *1.5.1 Primary Packaging*<br>1.5.1.1 Capsules, hard shell<br>1.5.1.8 Other solid dosage forms: Powders and Granules(en)<br>1.5.1.13 Tablets<br>Special Requirements<br>7 Other: Hormones or substances with hormonal activity: corticosteroid and sexual hormones excluded(en) |
| | *1.5.2 Secondary packaging* |

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| **1.6** | **Quality control testing** |
| | *1.6.1 Microbiological: sterility* |
| | *1.6.2 Microbiological: non-sterility* |
| | *1.6.3 Chemical/Physical* |
| | *1.6.4 Biological* |

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| **2 IMPORTATION OF MEDICINAL PRODUCTS** | |
| **2.1** | **Quality control testing of imported medicinal products** |
| | *2.1.3 Chemical/Physical* |

Clarifying remarks (for public users)

***1.1.1.2 Lyophilisates: Also biotechnology and immunological products ; 1.1.1.4 Small volume liquids: Also biotechnology and immunological products ; 1.1.3 Batch certification: Aseptically prepared products; 1.2.1.8 Other solid dosage forms: Podwers and Granules; 1.3.1.2 Immunological products: Allergens, recombinant vaccines (excluding active substance manufacturing); 1.3.1.5 Biotechnology products: Recombinant proteins, Monoclonal Antibodies; 1.5.1.8 Other solid dosage forms: Powders and Granules; 1.5.1.13 Tablets: Hormones or substances with hormonal activity: corticosteroid and sexual hormones excluded; 1.6.4 Biological: LAL test.***

***2020-09-10***

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

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***Confidential***
***Italian Medicines Agency***
Tel:***Confidential***
Fax:***Confidential***

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*Agenzia Italiana del Farmaco*

Certificado Nº: ***IT/100/H/2020***

# CERTIFICADO DE CUMPLIMIENTO DE NCF DE UN FABRICANTE [1,2]

## Parte 1

Emitido en virtud de una inspección según el

La autoridad competente de Italia confirma lo siguiente:
El fabricante: ***PATHEON ITALIA S.P.A.***
En su planta ubicada en: ***VIALE G.B. STUCCHI, 110, MONZA (MB), 20900, Italia***

Ha sido inspeccionado dentro del programa nacional de inspecciones y en relación con la autorización de laboratorio farmacéutico número ***aM79/2020*** de acuerdo con Art. 40 de la Directiva 2001/83/CE.

En base a la información obtenida en las visitas de inspección a este fabricante, la última de ellas realizada en ***2020-05-29***, se considera que el mismo cumple con:

Este certificado refleja la situación de la planta de fabricación en la fecha en que se efectúa la inspección antes citada, y no puede considerarse que acredite el cumplimiento si han transcurrido más de tres años desde esa fecha de inspección. Sin embargo, este período de validez podrá verse reducido o ampliado mediante el empleo de la herramienta de análisis de riesgos, debiendo incluirse en el correspondiente campo de Restricciones y Aclaraciones. Este certificado es válido sólo cuando se presente con todas las páginas y las Partes 1 y 2.La autenticidad de este certificado puede ser verificada en EudraGMDP. Si éste no aparece, por favor, contacte con la autoridad emisora

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[1] *El certificado al que se hace referencia en el párrafo 111(5) de la Directiva 2001/83/CE y 80(5) de la Directiva 2001/82/CE, deberá ser también requerido en las importaciones*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *Estos requisitos cumplen con las NCF de la OMS*

## Parte 2

| 1 Operaciones de Fabricación | |
|---|---|
| **1.1** | **Productos Estériles** |
| | *1.1.1 Preparación aséptica (operaciones de procesamiento de las siguientes formas farmacéuticas)*<br>1.1.1.2 Liofilizados<br>Requisitos especiales<br>7 Otros: Prostaglandins(en)<br>1.1.1.4 Líquidos de pequeño volumen<br>Requisitos especiales<br>7 Otros: Immunosuppressive(en) |
| | *1.1.2 Esterlización terminal (operaciones de procesamiento de las siguientes formas farmacéuticas)*<br>1.1.2.3 Líquidos de pequeño volumen |
| | *1.1.3 Certificacion de lotes* |
| **1.2** | **Productos no estériles** |
| | *1.2.1 Productos no estériles (operaciones de procesamiento de las siguientes formas farmacéuticas)*<br>1.2.1.1 Cápsulas duras<br>1.2.1.8 Otras formas farmacéuticas sólidas: Powders and Granules(en)<br>1.2.1.13 Comprimidos |
| | *1.2.2 Certificacion de lotes* |
| **1.3** | **Medicamentos biológicos** |
| | *1.3.1 Medicamentos biológicos*<br>1.3.1.2 Productos inmunológicos<br>1.3.1.5 Productos Biotecnológicos |
| **1.5** | **Acondicionamiento** |
| | *1.5.1 Acondicionamiento Primario*<br>1.5.1.1 Cápsulas duras<br>1.5.1.8 Otras formas farmacéuticas sólidas: Powders and Granules(en)<br>1.5.1.13 Comprimidos<br>Requisitos especiales<br>7 Otros: Hormones or substances with hormonal activity: corticosteroid and sexual hormones excluded(en) |
| | *1.5.2 Acondicionamiento secundario* |
| **1.6** | **Control de calidad** |

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| | *1.6.1 Microbiológico: estéril* |
| | *1.6.2 Microbiológico: no-estéril* |
| | *1.6.3 Químico/ Físico* |
| | *1.6.4 Biológico* |

| **2 IMPORTACION DE MEDICAMENTOS** | |
|---|---|
| **2.1** | **Actividades de control de calidad de medicamentos importados** |
| | *2.1.3 Químico/ Físico* |

Aclaraciones (para el público general)

***1.1.1.2 Lyophilisates: Also biotechnology and immunological products ; 1.1.1.4 Small volume liquids: Also biotechnology and immunological products ; 1.1.3 Batch certification: Aseptically prepared products; 1.2.1.8 Other solid dosage forms: Podwers and Granules; 1.3.1.2 Immunological products: Allergens, recombinant vaccines (excluding active substance manufacturing); 1.3.1.5 Biotechnology products: Recombinant proteins, Monoclonal Antibodies; 1.5.1.8 Other solid dosage forms: Powders and Granules; 1.5.1.13 Tablets: Hormones or substances with hormonal activity: corticosteroid and sexual hormones excluded; 1.6.4 Biological: LAL test.***

***2020-09-10***

Nombre y firma de la persona autorizada de la Autoridad Competente de Italia

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***Confidencial***
***Agenzia Italiana del Farmaco***
Tel:***Confidencial***
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