

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: 2020/HPF/FR/064

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: **PATHEON FRANCE**

Site address: **40 boulevard de Champaret, BOURGOIN JALLIEU, 38300, France**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **M 20/038** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

Art. L.5124-3 of Public Health Code

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-09-27**, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell Special Requirements 7 Other: highly potent products including "selective" cytostatics(en) 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: granules(en) Special Requirements 7 Other: granules of highly potent products including "selective" cytostatics(en) 1.2.1.13 Tablets Special Requirements 7 Other: highly potent products including hormones and "selective" cytostatics(en)
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.8 Other: capsules hard shell of bacterial spores(en)
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.8 Other: capsules, hard shell of bacterial spores(en)
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: highly potent products including "selective" cytostatics(en) 1.5.1.2 Capsules, soft shell 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: granules(en) 1.5.1.13 Tablets Special Requirements 7 Other: highly potent products including hormones and "selective" cytostatics(en)
	<i>1.5.2 Secondary packaging</i>

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

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
2.2	Batch certification of imported medicinal products
	2.2.2 Non-sterile products
2.3	Other importation activities
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

Signatory: Mr Said Ioughlissen, deputy head of pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good manufacturing practice certificates.

Vu exclusivement pour certification matérielle
de la signature de M. R. RUHEAU

le 11/06/20

2020-03-09

[Signature]

PR-AP

04 JUN 2020

Didier Ruheau



Pr le Président,

Angélique CONTAMIN

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

Fax: Confidential

APOSTILLE
(Convention de la Haye du 05 Octobre 1961)
----- CHILI -----

1. République Française
- Le présent acte public
2. a été signé par Mme Angélique CONTAMIN
3. agissant en qualité Assistante Réglementation
4. est revêtu du sceau de CCI Nord Isère
5. à Grenoble
- Attesté 6. le 24 juin 2020
7. par le Procureur Général près la Cour d'Appel de Grenoble
8. sous le N° RG 20/01553

9. Sceau :



10. Signature :

P/Le Procureur Général
G. AUGUSTE
AVOCAT GÉNÉRAL

"L'Apostille confirme seulement l'authenticité de la signature, du sceau ou timbre sur le document. Elle ne signifie pas que le contenu du document est correct ou que la République française approuve son contenu"