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ansm
Agence nationale de sécurité du médicament et des produits de santé

Direction de l'Inspection

Pôle Inspection des Produits Pharmaceutiques
et Lutte contre les Fraudes

A l'attention des pharmaciens responsables des établissements pharmaceutiques
Attention: Responsible Pharmacists of pharmaceutical companies

Saint-Denis, le 19 AVR. 2016

Madame, Monsieur,
Dear Sir or Madam,

Je vous informe qu'à compter du 15 avril 2016, l'ANSM ne délivre plus d'original signé des certificats de conformité aux bonnes pratiques de fabrication et de distribution en gros. Ces certificats sont en effet mis en ligne et librement consultables sur la base de données communautaire EudraGMDP (à partir du lien suivant : http://eudragmdp.ema.europa.eu/).
Starting from April 15th 2016, no hand signed original good manufacturing/distribution practice certificate will be issued by ANSM, which shares these certificates online in the public Community database EudraGMDP (http://eudragmdp.ema.europa.eu/).

Cette base de données a été mise en place en avril 2007 par l'Agence Européenne du Médicament (EMA) et à l'initiative de la Commission européenne afin notamment de :

- s'affranchir de la soumission de documents papier lors des demandes d'autorisation de mise sur le marché et des demandes de variations ;
- améliorer le partage d'informations entre les autorités compétentes et le public, y compris l'industrie pharmaceutique ;
- contribuer à la sécurisation de la chaîne de distribution des médicaments en facilitant les vérifications relatives à la qualification des différents acteurs.

This database was launched in April 2007 by the European Medicines Agency (EMA), at the initiative of the European Commission, particularly in order to:

- *eliminate the need for industry to submit paper documents to support marketing-authorisation and variation applications;*
- *improve the sharing of information between regulators and the public, including the pharmaceutical industry;*
- *help to protect the medicine distribution chain by facilitating the verification of legitimate actors.*

Les informations disponibles sur la base EudraGMDP sont fournies exclusivement par les autorités compétentes nationales à travers un réseau sécurisé garantissant leur authenticité et leur validité.
Information available in the EudraGMDP database is provided only by the national competent authorities through a secure network guaranteeing its authenticity and its validity.

Ce courrier est mis à votre disposition à titre informatif, afin notamment de vous aider dans vos démarches administratives, en particulier auprès des autorités nationales étrangères.
This information letter is also intended to help you with administrative applications in foreign countries.

Je vous prie d'agréer, Madame, Monsieur, l'assurance de ma considération distinguée.
Yours sincerely,

Le Directeur de l'Inspection

Gaëtan RUDANT

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French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***2019/HPF/FR/115***

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: ***FAREVA AMBOISE***
Site address: ***Zone Industrielle, 29 route des Industries, POCE SUR CISSE, 37530, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 17/091*** 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 ***2018-12-13*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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.

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[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	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 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) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: powder for oral suspension ; cutaneous patch (allergens)(en) 1.2.1.13 Tablets Special Requirements 7 Other: substances with hormonal activity(en)
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products 1.3.1.6 Human or animal extracted products
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.6 Human or animal extracted products

1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: powder for oral suspension ; cutaneous patch (allergens)(en) 1.5.1.13 Tablets Special Requirements 7 Other: substances with hormonal activity(en)
	1.5.2 Secondary packing
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*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical* *2.1.4 Biological*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	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)

Cet établissement a fait l'objet de deux inspections menées respectivement du 12 au 15 novembre 2018 (produits stériles) puis du 11 au 13 décembre 2018 (produits non stériles). 1.3 : limited to cutaneous patches - Signatory: Mr Said Ioughlissen, deputy head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue hard copies of good practice certificates.

2019-04-16

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

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Confidential
French National Agency for Medicines and Health Products Safety
Tel: ***Confidential***
Fax: ***Confidential***

PARQUET GENERAL ORLEANS

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE TOURAINE
Vu exclusivement pour certification matérielle de la signature de
M Eric MAO
(Seen exclusively to certify the above signature)
Pour le Président
C. FOLTRAN

Eric MAO
28 AVR. 2020
Pharmacien Responsable
AREVA AMBOISE

083988

CHAMBRE DE COMMERCE D'INDUSTRIE
JUIN 2020
TOURAINE

APOSTILLE
(Convention de la Haye du 5 octobre 1961)
CHILI

1. **République Française**
Le présent acte public

2. a été signé par C. FOLTRAN

3. agissant en qualité de chargée de relations clients

4. est revêtu du sceau/timbre de la Chambre de Commerce et d'Industrie de TOURAINE

Attesté

5. à **ORLEANS** 6. le 09 Juillet 2020

7. par le Procureur général près la Cour d'appel d'Orléans

8. sous le n°**923/2020**

9. sceau : 10. signature

P/Le Procureur Général

Luc BELAN
Avocat Général

PARQUET GENERAL ORLEANS

"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".