

Direction de l'inspectionPôle Inspection des Produits Pharmaceutiques
et Lutte contre les Fraudes

Dossier suivi par : Laila YAHI

Tél. : +33 (0)1 55 87 41 45

Fax. : +33 (0)1 55 87 39 72

Réf. : BPF n° HPF/FR/290/2015 – CM/LY

Madame Delphine ARGAUD-BONAITI
Pharmacien responsable
Société « AIR PRODUCTS »
45 avenue Victor Hugo – Bâtiment 270
Parc des Portes de Paris
93300 AUBERVILLIERSSaint-Denis, le **21 DEC. 2015**

Madame,

L'établissement pharmaceutique de votre entreprise implanté à Templemars (Nord), Zone Industrielle de l'Epinoy, a été inspecté du 8 au 10 septembre 2015.

Par conséquent, dans le cadre de la mise en application, sur le territoire national, de certaines dispositions de la directive 2001/83/CE modifiée, je vous prie de trouver, ci-joint, **l'original du certificat** de conformité aux bonnes pratiques de fabrication (BPF) de médicaments à usage humain [HPF/FR/290/2015].

J'attire votre attention sur le fait que l'ANSM ne délivre pas de copie certifiée de ces documents et vous invite en conséquence à vous rapprocher, en cas de besoin, des services administratifs locaux compétents.

Ce même certificat de conformité aux bonnes pratiques délivré par l'ANSM est librement consultable dans la banque de données communautaire EudraGMDP (à partir du lien suivant : <http://eudragmdp.ema.europa.eu/>).

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

La chef de pôle inspection des produits pharmaceutiques
et luttes contre les fraudes 1
Mélanie CACHET

French National Agency for Medicines and Health Products SafetyCERTIFICATE NUMBER: *HPF/FR/290/15***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: **AIR PRODUCTS - TEMPLEMARS**

Site address: **Zone Industrielle de l'Epinoy, TEMPLEMARS, 59175, France**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **M 15/138** 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 **2015-09-10**, 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 EudraGMP. 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.

La chef de pôle inspection des produits pharmaceutiques
et luttés contre les fraudes 1


Melanie CACHET

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>
	1.2.1.7 Medicinal gases
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packing</i>
	1.5.1.7 Medicinal gases
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

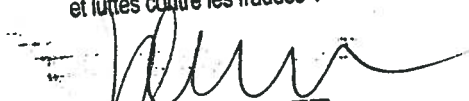
Clarifying remarks (for public users)

Types of gases manufactured : simple compressed gases, simple cryogenic gases (fixed and mobile cryogenic vessels), simple liquefied gases (cylinder and fixed vessels) Types of stored and distributed gases: simple compressed gases, simple cryogenic gases (mobile cryogenic vessels), simple liquefied gases (cylinder vessels), mixed gases

2015-12-18

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

La chef de pôle inspection des produits pharmaceutiques
et luttés contre les fraudes 1



Melanie CACHET

Ms. Melanie Cachet
French National Agency for Medicines and Health
Products Safety
Tel: +33 155873971
Fax +33 155873972