Agence nationale de sécurité du médicament et des produits de santé

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***HPF/FR/17/2016***

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: ***SYNERLAB DEVELOPPEMENT - ORLEANS***
Site address: ***1 rue Charles de Coulomb, ORLEANS, 45000, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 13/84*** 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 ***2013-01-24*** , 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 EudraGMP. 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.*

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

Mélanie CACHET

143/147 boulevard Anatole France - F-93285 Saint-Denis Cedex - Tél.: +33(0)1 55 87 30 00 - www.ansm.sante.fr

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
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: other.solid.dosage.forms(en) 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) 1.3.1.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packing
	1.5.1 Primary Packing 1.5.1.2 Capsules, soft shell
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

This good manufacturing practice certificate is valid until January 24th 2018. / Signatory: Mrs Mélanie Cachet, head of pharmaceutical product inspection and counterfeiting fight department.

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

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

2016-01-26

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

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

Mélanie CACHET

Ms. Melanie Cachet
French National Agency for Medicines and Health Products Safety
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Agence nationale de sécurité du médicament et des produits de santé

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***HPF/FR/18/2016***

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

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of France confirms the following:
The manufacturer: ***SYNERLAB DEVELOPPEMENT - ORLEANS***
Site address: ***1 rue Charles de Coulomb, ORLEANS, 45000, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 13/84*** in accordance with Art. 13 of Directive 2001/20/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 ***2013-01-24*** , it is considered that it complies with :

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

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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.*

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Agence nationale de sécurité du médicament et des produits de santé

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
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: other.solid.dosage.forms(en) 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) 1.3.1.2 Immunological products 1.3.1.5 Biotechnology products 1.3.1.6 Human or animal extracted products
1.5	**Packaging**
	1.5.2 Secondary packing
	1.5.1 Primary Packing 1.5.1.2 Capsules, soft shell
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.2 Immunological products 2.2.3.5 Biotechnology products 2.2.3.6 Human or animal extracted products

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

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Clarifying remarks (for public users)

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