National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER : ***2021/HPF/FR/167***

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 :***ABL EUROPE***
Site address :***4 rue Laurent Fries, ILLKIRCH GRAFFENSTADEN, 67400, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 20/056*** in accordance with Art. 13 of Directive 2001/20/EC .

Other
article 5 du règlement (CE) n° 1394/2007

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-04-01*** , 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 Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.4 Gene therapy products
	1.3.2 Batch Certification (list of product types) 1.3.2.4 Gene therapy products
1.5	**Packaging**
	1.5.2 Secondary packaging

Clarifying remarks (for public users)

Legal basis for inspection: EU GMP Part IV ---- This site is not authorised for blinding operations. Signatory: Mrs Florence Descamps-Delesalle, head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good manufacturing practice certificates.

2021-10-15

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

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Confidential
National Agency For The Safety Of Medicine And Health Products
Tel:***Confidential***
Fax:***Confidential***

National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER : ***2021/HPF/FR/164***

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 :***ABL EUROPE***
Site address :***400 boulevard Gonthier d'Andernach, ILLKIRCH GRAFFENSTADEN, 67400, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***F 16/039*** in accordance with Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-04-01*** , 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 Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
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

Clarifying remarks (for public users)

Signatory: Mrs Florence Descamps-Delesalle, head of the pharmaceutical product inspection and counterfeiting fight department--- The ANSM does not issue paper copies of good manufacturing practice certificates.

2021-10-15

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

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Confidential
National Agency For The Safety Of Medicine And Health Products
Tel:***Confidential***
Fax:***Confidential***

National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER : ***2021/HPF/FR/168***

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 :***ABL EUROPE***
Site address :***317 avenue Jean Jaurès, LYON, 69007, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 20/206*** in accordance with Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-07-09*** , 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 Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids 1.1.1.6 Other: manufacturing of biological investigational medicinal products limited to intermediate products(en)
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use 1.2.1.17 Other: suspension [intestinal use](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 1.3.1.4 Gene therapy products 1.3.1.5 Biotechnology 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 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use 1.5.1.17 Other non-sterile medicinal products: suspension [intestinal use](en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

This certificate is issued following inspections carried out from July 6th to 9th 2020 and from March 16th to 19th 2021 --- 1.5.2 : authorized for suspensions (intestinal use) only ; the site is not authorized for blinding operations --- Signatory: Mr Said Ioughlissen, deputy head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good manufacturing practice certificates.

2021-11-04

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

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Confidential
National Agency For The Safety Of Medicine And Health Products
Tel:***Confidential***
Fax:***Confidential***

MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	F 16/039
2. Name of authorisation holder	ABL EUROPE
3. Address(es) of manufacturing site(s)	ABL EUROPE - ILLKIRCH GRAFFENSTADEN, 400 boulevard Gonthier d'Andernach, ILLKIRCH GRAFFENSTADEN, 67400, France
4. Legally registered address of authorisation holder	4 rue Laurent Fries, ILLKIRCH GRAFFENSTADEN, 67400, France
5. Scope of authorisation and dosage forms [2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2016-02-01
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract laboratories) Annex 5 (Name of Qualified Person) Annex 6 (Name of responsible persons) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured/ imported products authorised) [3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, 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] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : ABL EUROPE - ILLKIRCH GRAFFENSTADEN, 400 boulevard Gonthier d'Andernach, ILLKIRCH GRAFFENSTADEN, 67400, France

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
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

MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	M 20/056
2. Name of authorisation holder	ABL EUROPE
3. Address(es) of manufacturing site(s)	ABL EUROPE, 4 rue Laurent Fries, ILLKIRCH GRAFFENSTADEN, 67400, France
4. Legally registered address of authorisation holder	4 rue Laurent Fries, ILLKIRCH GRAFFENSTADEN, 67400, France
5. Scope of authorisation and dosage forms [2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2020-04-20
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract laboratories) Annex 5 (Name of Qualified Person) Annex 6 (Name of responsible persons) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured/ imported products authorised) [3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, 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] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : ABL EUROPE, 4 rue Laurent Fries, ILLKIRCH GRAFFENSTADEN, 67400, France

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.3 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 1.3.1.4 Gene therapy products
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.4 Gene therapy products
1.5	**Packaging**
	1.5.2 Secondary packaging

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

Manufacturer (Article R.5124-2 1° of the French Public Health Code) --- This site is not authorised for blinding operations. Signatory: Mr Said Ioughlissen, deputy head of pharmaceutical product inspection and counterfeiting fight department. The ANSM does not issue hard copy of this authorisation.

MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	M 20/206
2. Name of authorisation holder	ABL EUROPE
3. Address(es) of manufacturing site(s)	ABL EUROPE - LYON, 317 avenue Jean Jaurès, LYON, 69007, France
4. Legally registered address of authorisation holder	4 rue Laurent Fries, ILLKIRCH GRAFFENSTADEN, 67400, France
5. Scope of authorisation and dosage forms [2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2020-12-11
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract laboratories) Annex 5 (Name of Qualified Person) Annex 6 (Name of responsible persons) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured/ imported products authorised) [3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, 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] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : ABL EUROPE - LYON, 317 avenue Jean Jaurès, LYON, 69007, France

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids 1.1.1.6 Other: manufacturing of biological investigational medicinal products limited to intermediate products(en)
	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 1.2.1.6 Liquids for internal use 1.2.1.15 Other: suspension [intestinal use](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 1.3.1.4 Gene therapy products 1.3.1.5 Biotechnology 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 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.6 Liquids for internal use

	1.5.1.15 Other non-sterile medicinal products: suspension [intestinal use](en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical 1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

Manufacturer (Article R.5124-2 1° of the French Public Health Code) 1.5.2 : authorized for suspensions (intestinal use) and capsules, hard shell only (1.2.1.1) ; the site is not authorized for blinding operations Signatory: Mr Said Ioughlissen, deputy head of pharmaceutical product inspection and counterfeiting fight department. The ANSM does not issue hard copy of this authorisation.