National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER: ***2021/HPF/FR/014_P_2023***

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: ***Ipsen Pharma Biotech***
Site address: ***No 402 Parc Activites Du Plat De, Signes, 83870, France***
OMS Organisation Id. / OMS Location Id.: ***ORG-100004020*** / ***LOC-100000863***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***2022_218_1_2*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-11-06***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Digitally signed by Chitic Vlad
Date: 2023.10.19 17:42:03 EEST
Reason: MoldSign Signature
Location: Moldova

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements 7 Other: hormones(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: cytotoxics(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.2 Semi-solids Special Requirements 7 Other: hormones(en) 1.1.2.3 Small volume liquids Special Requirements 7 Other: hormones(en) 1.1.2.4 Solids and implants Special Requirements 7 Other: hormones(en)
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packaging
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
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology 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)

This good practice certificate is valid until November 6th 2024. Manufacture : The site is authorised to the parametric release of the only medicinal products whose marketing authorisation includes this operation. --- Signatory: Mrs Solange Solbes, coordinator of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue hard copies of good practice certificates.

2023-07-03

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

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National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER: ***2021/HPF/FR/015_P_2023***

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: ***Ipsen Pharma Biotech***
Site address: ***No 402 Parc Activites Du Plat De, Signes, 83870, France***
OMS Organisation Id. / OMS Location Id.: ***ORG-100004020*** / ***LOC-100000863***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***2022_218_1_2*** 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 ***2020-11-06***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

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[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[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) 1.1.1.2 Lyophilisates Special Requirements 7 Other: hormones(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: cytotoxics(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.2 Semi-solids Special Requirements 7 Other: hormones(en) 1.1.2.3 Small volume liquids Special Requirements 7 Other: hormones(en) 1.1.2.4 Solids and implants Special Requirements 7 Other: hormones(en)
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packaging
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
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology 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)

This good practice certificate is valid until November 6th 2024. Manufacture : The site is authorised to the parametric release of the only medicinal products for which the clinical research authorisation includes this operation. --- The site is not authorised for blinding operations. --- Signatory: Mrs Solange Solbes, coordinator of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue hard copies of good practice certificates.

2023-07-03

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

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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: ***IPSEN PHARMA BIOTECH***
Site address: ***Parc d'Activités du Plateau de Signes, Chemin départemental N° 402, SIGNES, 83870, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 20/144*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-11-06***, 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements 7 Other: hormones(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: cytotoxics(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.2 Semi-solids Special Requirements 7 Other: hormones(en) 1.1.2.3 Small volume liquids Special Requirements 7 Other: hormones(en) 1.1.2.4 Solids and implants Special Requirements 7 Other: hormones(en)
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	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
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology 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)

Manufacture : The site is authorised to the parametric release of the only medicinal products whose marketing authorisation includes this operation. --- 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.

2021-02-05

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

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2023-07-03

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

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