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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/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2. (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.

- (1) The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is 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.

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

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

Confidential

National Agency For The Safety Of Medicine And Health Products

Tel: Confidential

Fax: Confidential

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Due to the restrictions caused by COVID-19, the period of validity of GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2024, except where clarifying remarks in the document state otherwise. Manufacturers, importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are now being conducted and scheduling of these inspections may be independent of the extended validity period stated above. Competent authorities will continue to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP and GDP certificates, as appropriate.

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

Documents issued by UK authorities up to and including 31 December 2020 remain available for consultation in EudraGMDP. However, they are no longer included or updated from 1 January 2021, with the exception of the documents pertaining to sites located in Northern Ireland.

As of 28 January 2022, the source of organisational data will change. Additional information and instructions are available on EMA's website

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