National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER: ***2024_HPF_FR_072***

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: ***Cis Bio International***
Site address: ***Saclay, 306 Route Nationale, Bp 32 Saclay, Gif Sur Yvette Cedex, 91192, France***
OMS Organisation Id. / OMS Location Id.: ***ORG-100003269*** / ***LOC-100001383***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***2024_137_1_2_3*** 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 ***2024-01-26***, 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.

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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.*

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 1.1.1.4 Small volume liquids Special Requirements 5 Radiopharmaceuticals
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids Special Requirements 5 Radiopharmaceuticals 1.1.2.5 Other: column of molybdenum-99 for radionuclide generator of technetium(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 Special Requirements 5 Radiopharmaceuticals 1.2.1.10 Radionuclide generators Special Requirements 5 Radiopharmaceuticals
	1.2.2 Batch certification

1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.1 Blood products Special Requirements 5 Radiopharmaceuticals 1.3.1.2 Immunological products Special Requirements 5 Radiopharmaceuticals 1.3.1.5 Biotechnology products Special Requirements 5 Radiopharmaceuticals 1.3.1.6 Human or animal extracted products Special Requirements 5 Radiopharmaceuticals
	1.3.2 Batch Certification (list of product types) 1.3.2.1 Blood products Special Requirements 5 Radiopharmaceuticals 1.3.2.2 Immunological products Special Requirements 5 Radiopharmaceuticals 1.3.2.5 Biotechnology products Special Requirements 5 Radiopharmaceuticals 1.3.2.6 Human or animal extracted products Special Requirements 5 Radiopharmaceuticals
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use Special Requirements 5 Radiopharmaceuticals 1.5.1.10 Radionuclide generators Special Requirements 5 Radiopharmaceuticals
	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
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.1 Blood products 2.2.3.2 Immunological products 2.2.3.5 Biotechnology products 2.2.3.6 Human or animal extracted 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)

1.1.2.5: the sterilization of the column of molybdenum-99 is followed by an aseptic connexion with a receiving recipient for radionuclide generator of technetium --- The site is allowed to manufacture radiopharmaceutical medicines, generators, kits and precursors stipulated in paragraph 7°, 8°, 9°, 10° of Article L.5121-1 of the French Public Health Code. --- 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.

2024-05-29

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

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