National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER: ***2020/HPF/FR/117***

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

Part 1

Issued following an inspection in accordance with :

The competent authority of France confirms the following:
The manufacturer: ***CIS BIO INTERNATIONAL***
Site address: ***Route Nationale 306, Saclay BP 32, GIF SUR YVETTE, 91192, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***MM 14/58*** 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 ***2020-01-31***, it is considered that it complies with:

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

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) 1.2.1.1 Capsules, hard shell Special Requirements 5 Radiopharmaceuticals 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 1.5.1.1 Capsules, hard shell Special Requirements 5 Radiopharmaceuticals 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)

Manufacture : 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 --- The site is not authorized for blinding operations --- Signatory: Mrs Mélanie Cachet, deputy director - Inspection division --- The ANSM does not issue hard copies of good practice certificates.

2020-08-07

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

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French National Agency for Medicines and Health Products Safety
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