Norwegian Medicines Agency

CERTIFICATE NUMBER : ***21/07443-11***

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
Art. 15 of Directive 2001/20/EC

The competent authority of Norway confirms the following:
The manufacturer :***GE Healthcare AS - Oslo Plant***
Site address :***Nycoveien 1, OSLO, NO-0485, Norway***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***21/22312-2*** in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC .

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

Other
Art. 13 of Directive 2001/20/EC
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-04-29*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]
- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC .

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.

[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 Medicinal Products 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 1.1.1.4 Small volume liquids Special Requirements 7 Other: Parenteral use(en) 1.1.1.6 Other: Evacuated and gas filled vials(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids Special Requirements 7 Other: Parenteral use(en) 1.1.2.3 Small volume liquids Special Requirements 7 Other: Parenteral use(en)
	1.1.3 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.3 Other: Reagent kits for manufacture of PET products | API(en)
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*

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*

2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

4. Other Activities - Active Substances :
The certificate also includes manufacture of Active Pharmaceutical Ingredients that are approved for specific clinical trials.

Clarifying remarks (for public users)

Section 1.4.1.3 covers batch certification and includes parametric release in manufacture of Omnipaque, Visipaque, Omniscan and Clariscan in glass vials, Omnipaque and Clariscan in polypropylene bottles and Omniscan and Clariscan in prefilled syringes, but only where parametric release is approved under the specific product marketing authorisation. | The authorisation covers importation of the following medicinal products from the USA and Canada: Pre-Filled Normal Saline Flush Syringe 0.9 % Sodium Chloride Injection USP, Sodium Phosphate Buffered Solution 0.003 M inj., and Methylene Blue Inj. 1 % USP | The authorisation covers importation of the following products from China: Clariscan 367,9 mg/ml, Omnipaque (240, 300 and 350 mg I/ml), Accupaque (240, 300 and 350 mg I/ml) and Visipaque (270 and 320 mg I/ml) in glass vials or in polypropylene bottles. | The importation activity which applies to Human Investigational Medicinal Products is section 2.3.2, and covers importation from USA.

2021-07-02

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

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Confidential
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