Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten - Agence Fédérale des Médicaments et des Produits de Santé

CERTIFICATE NUMBER :***BE/GMP/2018/097***

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 Belgium confirms the following:

The manufacturer :***Janssen Pharmaceutica NV***

Site address : ***Turnhoutseweg 30, Beerse, 2340, Belgium***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***2 IMP*** 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 ***2018-06-22*** , 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. 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 Investigational Medicinal Products

1 MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)
1.1.1.4 Small volume liquids
1.1.2 Terminally Sterilised (processing operations for the following dosage forms)
1.1.2.3 Small volume liquids
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
1.2.1.5 Liquids for external use
1.2.1.6 Liquids for internal use
1.2.1.8 Other solid dosage forms: Powders and granulates(en)
1.2.1.13 Tablets
1.2.2 Batch certification

1.3 Biological medicinal products (list of product types)

1.3.1 Biological medicinal products (list of product types)
1.3.1.2 Immunological products
Special Requirements:
7 Other: Limited to thawing, mixing and filling of externally manufactured bulk solutions.(en)
1.3.1.5 Biotechnology products
Special Requirements:
7 Other: Limited to formulation and filling.(en)
1.3.2 Batch Certification (list of product types)
1.3.2.2 Immunological products
1.3.2.3 Cell therapy products
1.3.2.5 Biotechnology products

1.4 Other products or manufacturing activity

1.4.1 Manufacture of
1.4.1.4 Other: Challenging agents, limited to packaging and batch certification.(en)

1.5 Packaging

1.5.1 Primary Packaging
1.5.1.1 Capsules, hard shell
1.5.1.5 Liquids for external use
1.5.1.6 Liquids for internal use
1.5.1.8 Other solid dosage forms: Powders and granulates(en)
1.5.1.13 Tablets
1.5.2 Secondary packaging

2 IMPORTATION OF MEDICINAL PRODUCTS
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* 2.2.3.2 Immunological products 2.2.3.3 Cell therapy products 2.2.3.5 Biotechnology products
2.3 Other importation activities
2.3.2 Importation of intermediate which undergoes further processing *2.3.4 Other: Biological active substance; challenging agents.(en)*

2018-10-25

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

Confidential

Federal Agency for Medicines and Health Products

Tel :***Confidential***

Fax :***Confidential***

Digitally signed by Chirtoacă Iurie
Date: 2021.12.13 10:52:05 EET
Reason: MoldSign Signature
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