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Federal Agency For Medicines And Health Products

CERTIFICATE NUMBER: ***BE/GMP/2023/059***

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

Part 1

Issued following an inspection in accordance with
Art. 63 of Regulation (EU) 536/2014

The competent authority of Belgium confirms the following:
The manufacturer: ***Janssen Pharmaceutica***
Site address: ***Turnhoutseweg 30, Beerse, 2340, Belgium***
OMS Organisation Id. / OMS Location Id.: ***ORG-100000625*** / ***LOC-100005958***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***2 IMP*** in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-03-31***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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. 15 of Directive 2001/20/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

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: powder and granulates(en) 1.2.1.13 Tablets 1.2.1.14 Transdermal patches
	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 1.3.1.5 Biotechnology products
	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 1.4.1.3 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 1.5.1.14 Transdermal patches
	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 2.2.3.2 Immunological products 2.2.3.3 Cell therapy products 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing
	2.3.3 Biological active substance
	2.3.4 Other: Challenging agents(en)

Clarifying remarks (for public users)

1.1.3: Batch certification of sterile products, including radio-labelled products. 1.3.1.2. Limited to thawing, mixing and filling of externally manufactured bulk solutions 1.3.1.5. Limited to formulation and filling 2.3.2: Partially produced biotechnology products, granulates, powders, non-coated tablets.

2023-10-17

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

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Tel:***Confidential***
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