

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Land/Pays/Land	BELGIË - BELGIQUE - BELGIEN
2. Deze openbare akte is ondertekend door : Le présent acte a été signé par : Diese öffentliche Urkunde ist unterschrieben von :	De Buck Philippe
3. Handelend in hoedanigheid van : Agissant en qualité de : In seiner/ihrer Eigenschaft als :	Adviseur/Conseiller/Berater
4. Is voorzien van het zegel van : Est revêtu du sceau de : Sie ist versehen mit dem Siegel des/der :	FAGG/AFMPS/FAGG/FAMPS
Voor echt verklaard / Attesté / Bestätigt	
5. Te Brussel/A Bruxelles/In Brüssel	6. Op/Le/Am : 19/08/2020
7. Door FOD Buitenlandse Zaken, Buitenlandse Handel en Ontwikkelingssamenwerking Par le SPF Affaires étrangères, Commerce extérieur et Coopération au Développement Durch FÖD Auswärtige Angelegenheiten, Außenhandel und Entwicklungszusammenarbeit	
8. Onder Nr./Sous le n°/Unter Nr. : 200851912156	
9. Stempel/Sceau/Stempel:	10. Ondertekening/Signature/Unterschrift:
	

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Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: **BE/GMP/2017/043**

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 Belgium confirms the following:

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

Site address: ***Janssen Pharmaceuticaaan 3, Geel, 2440, Belgium***

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

Article 12 bis, § 4 of the Law of 25th March 1964 related to the Medicinal Products and Article 80 of the royal decree of 14 December 2006 related to medicinal products for human and veterinary use

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2017-05-19**, it is considered that it complies with :

- The principles of GMP for active substances³ 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

1 MANUFACTURING OPERATIONS	
1.6	Quality control testing
	1.6.3 Chemical/Physical

4. Other Activities - Active Substances :

1.6.3. Only for the following active substances or intermediates: KETOCONAZOLE - ENILCONAZOLE - ITRACONAZOLE - FENTANYL- FENTANYL CITRATE - DOMPERIDONE - ALFENTANYL HCL- KETANSERIN - KETANSERIN TARTRATE - ETRAVIRINE - LEVOCABASTINE HCL- RISPERIDONE - GALANTAMINE HYDROBROMIDE - PIPAMPERONE HCL - MICONAZOLE NITRATE - NEBIVOLOL HCL - HALOPERIDOL DECANOATE - HALOPERIDOL - PRUCALOPRIDE SUCCINATE- FLUSPIRILENE- BUPRENORPHINE - TAPENTADOL - RILPIVIRINE - BROMPERIDOL DECANOATE - MICONAZOLE - LOPERAMIDE HCL- PALIPERIDONE - PALIPERIDONE PALMITATE - DOMPERIDONE MALEATE- DAPOXETINE HCL - CANAGLIFLOZIN - SIMEPREVIR - RILPIVIRINE HCL - AZAPERONE - PIRITRAMIDE - PIMOZIDE - FLUNARIZINE DIHCL - ETOMIDATE- SUFENTANIL CITRATE - CLOSANTEL SODIUM - BUPRENORPHINE HCL- PARCONAZOLE HCL- LOPERAMIDE OXIDE- DICLAZURIL - ABIRATERONE ACETATE - BEDAQUILINE - TELAPREVIR - CINNARIZINE - DARUNAVIR

Clarifying remarks (for public users)

The duration of validity of this GMP-certificate has been extended with 1 year.

2020-03-17

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

on behalf Philippe De Buck, DG Inspection - Head of Division Authorisations

Mr. Xavier De Cuyper
Federal Agency for Medicines and Health Products
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