Ministero dell'Economia e delle Finanze
MARCA DA BOLLO
€16,00

Agenzia Italiana del Farmaco

AIFA

CERTIFICATE NUMBER: *IT/GMP/E/11/2017*

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 Italy confirms the following:
The manufacturer: ***Janssen-Ortho LLC***
Site address: ***State Road 933 Km 0.1, Mamey Ward, Gurabo, Puerto Rico, 00778, United States***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004 and Art. 19(3) of Regulation 726/2004/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-04-28*** , 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.

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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.*

SAEMID LÓPEZ CUZMÁN
ABOGADA-NOTARIA

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
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 1.2.1.13 Tablets
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate :

Inspection related to the following products: Invokana (Film-coated tablet); Vokanamet (Film-coated tablet); Rezolsta (Film-coated tablet); Prezista (Film-coated tablet); Topamax (capsules) Sprinkle (capsules). Only microbiolgical stability testing for Olysio (Capsule, hard); Imbruvica (Capsule, hard); Endurant (Film-coated tablet) and Intelence Tablet

Clarifying remarks (for public users)

Inspection related to the following products: Invokana (Film-coated tablet); Vokanamet (Film-coated tablet); Rezolsta (Film-coated tablet); Prezista (Film-coated tablet); Topamax (capsules) Sprinkle (capsules). Only microbiolgical stability testing for Olysio (Capsule, hard); Imbruvica (Capsule, hard); Endurant (Film-coated tablet) and Intelence Tablet

2017-08-31

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

AGENZIA ITALIANA DEL FARMACO

È copia conforme all'originale
composta di n. 2 fogli
Roma li .....

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