ansm
Agence nationale de sécurité du médicament et des produits de santé

RÉPUBLIQUE FRANÇAISE

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***2018MPP069VFR01***

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

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of France confirms the following:
The manufacturer: ***IONISOS***
Site address: ***Zone industrielle, CHAUMESNIL, 10500, France***

Is an active substance manufacturer that has been inspected in accordance with Art. 80(1) of Directive 2001/82/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-07-06*** , it is considered that it complies with :

- The principles of GMP for active substances [3] referred to in Article 51 of Directive 2001/82/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.*

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Part 2

Manufacture of active substance. Names of substances subject to inspection :
ACTIVE SUBSTANCES(en) / SUBSTANCES ACTIVES(fr)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : ACTIVE SUBSTANCES	
3.5	**General Finishing Steps**
	3.5.4 Other : Treatment by accelerated electron beam

Clarifying remarks (for public users)

Certificate limited to treatment by accelerated electron beam of packaged pharmaceutical ingredients : - Sterilization - Microbiological decontamination Certificat limité aux opérations de traitement par flux d'électrons accélérés d'ingrédients pharmaceutiques conditionnés : - Stérilisation - Décontamination microbiologique

2018-09-19

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

Madame Linda GALLAIS
Cheffe du pôle inspection des matières premières
Direction de l'inspection

Linda Gallais
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