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
French National Agency for Medicines and Health Products Safety
Tel:
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alimentation, environnement, travail

Certificat No : 15/125300

Certificate No: 15/125300

CERTIFICAT DE CONFORMITE AUX BPF POUR UN FABRICANT
CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Partie 1
Part 1

Délivré à la suite d'une inspection selon les dispositions de l'Article 80(5) de la Directive 2001/82/EC,
Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC,

L'autorité compétente **Anses ANMV (FRANCE)** confirme les éléments suivants :
*The competent authority of **Anses ANMV (FRANCE)** confirms the following:*

Le fabricant **IONISOS**
The manufacturer

Adresse du site **ZI DE BEAUVOIR, CHAUMESNIL, 10500 BRIENNE LE CHATEAU**
Site address

a été inspecté dans le cadre du programme national d'inspection en application des dispositions des articles L.5142-3 et R.5142-43 du code de la santé publique.
Has been inspected under the national inspection programme in accordance with Articles L.5142-3 and R.5142-43 of the public health code.

Au vu des éléments constatés lors de l'inspection menée dans cet établissement le **06/05/2015**, il apparaît que le fonctionnement de celui-ci est conforme aux principes et lignes directrices des bonnes pratiques de fabrication établis dans la directive 91/412/CEE[1].
*From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **May 6th 2015**, it is considered that it complies with The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC[2].*

Ce certificat reflète l'état de l'établissement de fabrication à la date de l'inspection précitée pour une durée de trois ans. Toutefois, cette période de validité peut être réduite ou prolongée par l'application des principes réglementaires de gestion du risque et par une mention dans le champ "restrictions ou clarifications". Ce certificat n'est valide que s'il est présenté avec toutes ses pages et les parties 1 et 2.
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.

L'authenticité de ce certificat peut être vérifiée auprès de l'autorité compétente.
The authenticity of this certificate may be verified with the issuing authority.

[1] *Ces exigences répondent aux recommandations de l'OMS*
[2] *These requirements fulfil the GMP recommandations of WHO.*

Partie 2
Part 2

☒ Médicaments vétérinaires / *Veterinary Medicinal Products*	
1. OPERATIONS DE FABRICATION DE MEDICAMENTS VETERINAIRES / *MANUFACTURING OPERATIONS OF VETERINARY MEDICINAL PRODUCTS*	
1.4	**Autres produits ou opérations pharmaceutiques / *Other products or manufacturing activity***
	1.4.2 Stérilisation de substances actives, excipients, produits finis / *Sterilisation of active substances, excipients, finished Products* 1.4.2.6 Irradiation beta / *Electron beam*

Restrictions ou précisions concernant la portée de ce certificat : Néant
Any restrictions or clarifying remarks related to the scope of this certificate: None

Ce certificat est valable jusqu' au 05/05/2020
This certificate is valid until May 5th 2020

23/07/2015

Nom et signature de la personne responsable de l'autorité compétente française (Anses-ANMV)
Name and signature of the authorized person of the Competent Authority of FRANCE

FOR THE DIRECTOR,
BY DELEGATION AND BY HINDRANCE,
The Head of the Unit responsible
for manufacturing authorizations
of the National agency for veterinary medicinal products

Nathalie LEGRAND