National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER: ***22MPP075HVFR02***

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

Part 1

Issued following an inspection in accordance with
Art. 94(1) of Regulation (EU) 2019/6 as amended
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of France confirms the following:
The manufacturer: ***Ionisos***
Site address: ***Zone Industrielle De L Aubree, Sable Sur Sarthe, 72300, France***
OMS Organisation Id. / OMS Location Id.: ***ORG-100018490*** / ***LOC-100067108***

Is an active substance manufacturer that has been inspected in accordance with Art. 123(6) of Regulation (EU) 2019/6 and Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-10-12***, it is considered that it complies with:

- The principles of GMP for active substances [3] referred to in and 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. 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.

---

[1] *The certificate referred to in paragraph Art. 80(5) of Directive 2001/82/EC and Art. 111(5) of Directive 2001/83/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

Human Medicinal Products
Veterinary Medicinal Products

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

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:ACTIVE SUBSTANCES

3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Gamma ray treatment of packaged pharmaceutical ingredient

Clarifying remarks (for public users)

This inspection was carried out with reference to the applicable guidelines, including EU GMP part II : Basic requirements for active substances used as starting materials // Period of validity of the certificate extended to 11/10/2026 // Signatory : Mrs Aurélie Demarcq, head of starting materials inspection department --- The ANSM does not issue hard copies of good practices certificates

2025-06-13

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

---

Confidential
National Agency For The Safety Of Medicine And Health Products
Tel:***Confidential***
Fax:***Confidential***