Italian Medicines Agency

CERTIFICATE NUMBER: ***IT/68/H/2020***

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

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of Italy confirms the following:
The manufacturer: ***FALORNI S.R.L.***
Site address: ***VIA DEI FRILLI, 25, SESTO FIORENTINO (FI), 50019, Italy***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***aM62/2020*** in accordance with Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-05-21*** , 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.

---

[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

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.5	**Packaging**
	1.5.2 Secondary packaging

Clarifying remarks (for public users)

From the knowledge gained during a distant assessment that was carried out due to the restrictions caused by COVID-19, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC. A on-site inspection should be conducted when circumstances permit. This certificate reflects the status of the manufacturing site at the time of the distant assessment noted above and is valid until 31/12/2021

2020-06-03

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

---

Confidential
Italian Medicines Agency
Tel: ***Confidential***
Fax: ***Confidential***