National Organization for Medicines

CERTIFICATE NUMBER : ***109283/ 15-11-2021***

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

Part 1

Issued following an inspection in accordance with :

The competent authority of Greece confirms the following:
The manufacturer :***ΦΑΡΜΑΚΑΠΟΘΗΚΗ ΑΛΦΑ-ΩΜΕΓΑ Α.Ε./ PHARMAKAPOTHIKI ALFA-OMEGA S.A.***
Site address :***ΛΑΚΚΟ ΚΥΡΙΛΛΟ, Τ.Θ. 152 / LAKKO KYRILLO, PO BOX.: 152, ΑΣΠΡΟΠΥΡΓΟΣ ΑΤΤΙΚΗΣ / ASPROPYRGOS ATTIKI, 193 00, Greece***
OMS Location :

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***0000011450/21/3*** in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
ΔΥΓ 3/89292/03, Art. 12
Δ.ΥΓ 3(α)/Γ.Π. 32221/29-4-2013, art. 57

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-10-18*** , it is considered that it complies with :

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.*

Part 2

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packaging

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Any restrictions related to the scope of this certificate :

Manufacturing activities are carried out in Building D.

Clarifying remarks (for public users)

Manufacturing activities are carried out in Building D.

2021-12-22

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

Dimitrios Dimas
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