National Organization for Medicines

CERTIFICATE NUMBER: ***40188/12-5-2016***

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

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended
Art. 15 of Directive 2001/20/EC

The competent authority of Greece confirms the following:
The manufacturer: ***ΦΑΡΜΑΤΕΝ ΑΒΕΕ / PHARMATHEN SA***
Site address: ***Δερβενακίων 6 / Derwenakion 6, Παλλήνη Αττικής / Pallini Attiki, 15351, Greece***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***0000006501/15/I*** in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC transposed in the following national legislation:
Δ.ΥΓ 3(α)/Γ.Π. 32221/29-4-2013, art. 57
ΔΥΓ 3/89292/03, Art. 12

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-04-08*** , 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.

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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

Human Medicinal Products Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.13 Tablets
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.6 Human or animal extracted products
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.5 Liquids for external use 1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical*
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 :

Storage of semifinished and finished products, packaging materials, starting materials, cosmetic products and medical devices, in the warehouse in Afoi Ksintara road, Pikermi Atiiki, Greece Storage of pharmaceutical starting materials, semifinished, finished medicinal products and packaging materials, in the warehouse in NATO Avenue, Site Aspropyrgos, Aspropyrgos, Attiki, Greece.

Clarifying remarks (for public users)

Storage of semifinished and finished products, packaging materials, starting materials, cosmetic products and medical devices, in the warehouse in Afoi Ksintara road, Pikermi Atiiki, Greece Storage of pharmaceutical starting materials, semifinished, finished medicinal products and packaging materials, in the warehouse in NATO Avenue, Site Aspropyrgos, Aspropyrgos, Attiki, Greece.

2016-09-01

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

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National Organization for Medicines
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Fax: *+30 210 6549 500*

ΑΚΡΙΒΕΣ ΦΩΤΟΑΝΤΙΓΡΑΦΟ
Από το πρωτότυπο που τηρείται
στον οικείο φάκελλο της υπηρεσίας
Χολαργός 31-10-16

Η ΔΙΕΥΘΥΝΤΡΙΑ Ε.Π.Κ.Π.
Π. ΓΚΟΥΡΑ

APOSTILLE - Επισημείωση

(CONVENTION DE LA HAYE DU 5 OCTOBRE 1961
Σύμβαση της Χάγης της 5ης Οκτωβρίου 1961)

1. Χώρα: ΕΛΛΑΣ
PAYS: HELLAS

Το παρόν δημόσιο έγγραφο
LE PRÉSENT ACTE PUBLIC

2. έχει υπογραφεί από τον/την: ΓΚΟΥΡΑ ΠΑΝΤΕΛΙΑ
A ÉTÉ SIGNÉ PAR:

3. που ενέργησε με την ιδιότητα: ΠΡΟΙΣΤΑΜΕΝΗ
AGISSANT EN QUALITÉ DE:

4. φέρει τη σφραγίδα/επίσημα του φορέα: ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ (Ε.Ο.Φ.)
EST REVETU DU SCEAU/
TIMBRE DE:

Η βεβαίωση χορηγείται/ATTESTÉ

5. στην ΑΘΗΝΑ
À ATHÈNES

6. την(ημερομηνία) 11/11/2016
LE

7. από την ΑΠΟΚΕΝΤΡΩΜΕΝΗ ΔΙΟΙΚΗΣΗ ΑΤΤΙΚΗΣ
PAR L' ADMINISTRATION DÉCENTRALISÉE DE L' ATTIQUE

8. με αριθμό 71565
SOUS No

9. Σφραγίδα/επίσημα
SCEAU/TIMBRE

10. Υπογραφή
SIGNATURE

ΚΟΝΙΑΡΗ Π ΕΛΕΝΗ


ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΑΠΟΚΕΝΤΡΩΜΕΝΗ ΔΙΟΙΚΗΣΗ ΑΤΤΙΚΗΣ