National Organization for Medicines

CERTIFICATE NUMBER: *82818/ 1-8-2018*

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: *PHARMATHEN INTERNATIONAL SA*
Site address: *ΒΙΟ.ΠΑ. Σαπών Νομού Ροδόπης/ Industrial Park Sapes Rodopi Prefecture, Οικοδομικό Τετράγωνο No 5/ Block No 5, Ροδόπη / Rodopi, 69300, Greece*

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. *0000007311/16/1* 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

Other :
-

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on *2018-06-22* , 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 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) 1.1.1.4 Small volume liquids 1.1.1.5 Solids and implants
	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 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Manufacture of active substance. Names of substances subject to inspection :
CHOLECALCIFEROL CONCENTRATE(en) - confidential

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance : CHOLECALCIFEROL CONCENTRATE - **confidential**	
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Physical processing: mixing 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Any restrictions related to the scope of this certificate :

1.1.1.5. Dry Injectables

Clarifying remarks (for public users)

1.1.1.5. Dry Injectables

2018-09-26

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 20-12-18

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΑΝΤΙΓΡΑΦΟ ΣΥΝΤΡΙΑ 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: ΠΡΟΪΣΤΑΜΕΝΗ
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) 18/2/2019
LE

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

8. με αριθμό 10910
SOUS No

9. Σφραγίδα/επίσημα
SCEAU/TIMBRE

10. Υπογραφή
SIGNATURE

ΤΟΥΣΗΣ
ΑΡΙΣΤΟΤΕΛΗΣ


ΑΠΟΚΕΝΤΡΩΜΕΝΗ ΔΙΟΙΚΗΣΗ ΑΤΤΙΚΗΣ