National Organization For Medicines

CERTIFICATE NUMBER: ***323129/ 31-3-2023***

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 S.A.***
Site address: ***Block No 5, Sapes Rodopi Prefecture, Industrial Park, Sapes, 693 00, Greece***
Additional details on units inspected: ***ΒΙΟ.ΠΑ. Σαπών Νομού Ροδόπης, Οικοδομικό Τετράγωνο Νο 5, Ροδόπη, 693 00, Ελλάδα***
OMS Organisation Id. / OMS Location Id.: ***ORG-100043114*** / ***LOC-100072733***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***0000007311/23/2*** in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC.

Other
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From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-12-09***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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 Art. 111(5) of Directive 2001/83/EC and Art. 15 of Directive 2001/20/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) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.5 Solids and implants
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.2 Semi-solids 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 1.2.1.8 Other solid dosage forms: Powder for oral suspension(en) 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.8 Other solid dosage forms: Powder for oral suspension(en) 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

1.1.1.5. Dry Injectables 1.6 Quality Control: Under Biological controls only LAL test is performed. Storage of pharmaceutical starting materials, packaging materials and finished products for human use in the warehouse located in Industrial Park Sapes Rodopi Prefecture, Block No 6, Rodopi

2023-05-10

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

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National Organization For Medicines
Tel:***Confidential***
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