National Organization for Medicines

CERTIFICATE NUMBER: ***3218/ 11-1-2022***

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: ***ΧΗΜΙΚΑ & ΒΙΟΦΑΡΜΑΚΕΥΤΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ΠΑΤΡΩΝ Α.Ε. / CHEMICAL AND BIOPHARMACEUTICAL LABORATORIES OF PATRAS S.A.***
Site address: ***Βιομηχανική Περιοχή Πατρών, οικοδομικό τεράγωνο 1 / Industrial Area of Patras, block 1, Πάτρα Αχαϊα / Patra Achaia, 25018, Greece***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***0000009662/21/1*** in accordance with Art. 44 of Directive 2001/82/EC, Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC.

Other
Γενική Επιθεώρηση GMP / General GMP Inspection

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-12-02***, 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**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.3 Chemical/Physical*

Manufacture of active substance. Names of substances subject to inspection:
AMINOACIDS(en)
PEPTIDES(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:AMINOACIDS

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: Purification by preparative HPLC
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared 3.4.2 Terminally sterilised
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying and Lyophillization 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 3.6.3 Microbiological testing including sterility testing

Active Substance:PEPTIDES

3.1	**Manufacture of Active Substance by Chemical Synthesis**

	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: Purification by preparative HPLC
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared 3.4.2 Terminally sterilised
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying and Lyophillization 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 3.6.3 Microbiological testing including sterility testing

2022-01-18

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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