

ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ

REPUBLIC OF CYPRUS MINISTRY OF HEALTH

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cp FOODLAB LTD

ΦΑΡΜΑΚΕΥΤΙΚΕΣ ΥΠΗΡΕΣΙΕΣ 1475 ΛΕΥΚΩΣΙΑ

PHARMACEUTICAL SERVICES 1475 LEFKOSIA

September 2, 2016

Inspection of the Analytical Laboratory cp FOODLAB Inspection no.: 16/2016, date inspection ended: 26th February 2016 Good Manufacturing Practice (GMP) Certificate no.: FDLB/2016/001

Please find, herewith attached, the GMP Certificate for the above mentioned manufacturing facility.

The Certificate is issued in accordance to the provisions of article 48(8)(a) of the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law No. 70(I) of 2001 [Article 111(5) of the Directive 2001/83/EC].

This Certificate is also published in the EudraGMP European Database (http://eudragmp.eudra.org/).

Anna Paphitou Head GMP Inspector

Pharmaceutical Services Ministry Of Health

CERTIFICATE NUMBER: FDLB/2016/001

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

The competent authority of Cyprus confirms the following:

The manufacturer: cp FOODLAB Ltd

Site address: 25 POLYPHONTI STREET, STROVOLOS, NICOSIA, 2047, Cyprus

Has been inspected under the national inspection programme in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

PART IV, Chapters A and B of the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law No 70(I) of 2001, as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2016-02-26, it is considered that it complies with :

• The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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 | | | | | |
|--------------------------|--------------------------------------|--|--|---|--|
| 1 MA | ANUFACTURING OPERATIONS | | | | |
| 1.6 | Quality control testing | | | * | |
| | 1.6.1 Microbiological: sterility | | | | |
| | 1.6.2 Microbiological: non-sterility | | | | |
| | 1.6.3 Chemical/Physical | | | | |

Any restrictions related to the scope of this certificate :

The scope of this GMP Certificate is restricted to 1) Chemical & Microbial testing (Total count, Pseudomonas aeroginosa, Legionella, E.coli, enterococcus, sterility testing) for water samples 2) Microbial testing for environmental monitoring samples 3) Chemical testing for ethanol and Cetalkonium in some finished pharmaceutical products 4) Microbial testing for finished drug products: Total viable count, E.coli, Salmonella, Yeast & moulds, Candida, Fungi, Pseudomonas aeruginosa, Enterobacteriaceae

2016-09-02

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

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