Certificate No: GMP 151/6

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with the requirements of Good Manufacturing Practice, of the Israeli laws and regulations (Pharmacist Regulations [Good Manufacturing Practice for Medicinal Products] 2008)

and

Issued under the provisions of the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel

The competent authority of Israel confirms the following:

The manufacturer **AMINOLAB Ltd.**

Site address **1 Pinchas Sapir St., Weizmann Science Park, POB 4074, Ness Ziona, Israel**

Has been inspected under the Israeli inspection programme, in accordance with the above mentioned laws and regulations

and

Has been inspected as a contract laboratory, that performs testing for other parties

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **24-25 SEPTEMBER 2017**, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel and the above mentioned Israeli laws and regulations (*).

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 EudraGMP. If it does not appear, please contact the issuing authority.

(*) these requirements fulfill the GMP recommendations of WHO

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המכון לביקורת ותקנים של חומרי רפואה
אגף הרוקחות
חטיבת טכנולוגיות רפואיות, מידע ומחקר
משרד הבריאות
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Part 2

1. MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS
1.6 Quality control testing
1.6.1 Microbiology: sterility
1.6.2 Microbiology: non-sterility
1.6.3 Chemical/Physical
3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES
3.6 Quality Control Testing
3.6.1 Physical / Chemical testing
3.6.3 Microbiological testing (including sterility testing)

Any restrictions or clarifying remarks related to the scope of this certificate:

The certificate holder is a contract laboratory that performs the following Pharmacopoeial tests:

- Microbiological examination of sterile products
- Microbiological examination of non-sterile products
- Bacterial Endotoxins Testing
- Antimicrobial Effectiveness Testing
- Verification of Spore Population in Biological Indicators
- Bioburden- Determination of a population of microorganisms on products
- Tests for environmental monitoring- Determination of a population of microorganisms on surfaces and air
- Physical/ Chemical testing of products/ raw materials including APIs by ICP-MS (Inductively Coupled Plasma Mass Spectrometry)
- Physical/ Chemical testing of products/ raw materials including APIs by GC-FID and Tripe Quadrupole GC-MS (Gas Chromatography Mass Spectrometry)
- Physical/ Chemical testing of products/ raw materials including APIs by HPLC (High Pressure/Performance Liquid Chromatography) , LC-MS (Liquid Chromatography Mass Spectrometry) and ICP (*Inductively_coupled_plasma*)
- Physical/ Chemical testing of products/ raw materials including APIs by IC (Ion-exchange chromatography)
- Total organic carbon determination

Name and signature of the authorized person of the Competent Authority of Israel:

Rina Heimlich, GMP Inspector

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MINISTRY OF HEALTH JERUSALEM
GOV. INSTITUTE FOR CONTROL AND STANDARD OF PHARMACEUTICALS
משרד הבריאות

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