Certificate No: **GMP 136/11**

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 **HY Laboratories Ltd.**

Site address **6 Menachem Plaut St., Tamar Park, Rehovot, 7670606, Israel**

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

and

Is a contract laboratory that performs QC testing of pharmaceuticals for other parties

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **3, 4 October 2021,** 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

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

20 -12- 2021

The Institute for Standardization and Control of Pharmaceuticals
Pharmaceutical Administration, Ministry of Health
9 Ya'akov Eli'av St., Jerusalem 9546208, Israel
Tel: +972-2-6551717 Fax: +972-2-6551777

וכון לביקורת ותקנים של חומרי רפואה
ף הרוקחות, משרד הבריאות
וב יעקב אליאב 9, ירושלים 9546208
02-6551777 פקס 02-6551717

Part 2

Human Products, Human Investigational Products, Veterinary Products
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 1.6.4 Biological
3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES 3.6 Quality Control Testing 3.6.1 Chemical/physical testing 3.6.3 Microbiological testing (including sterility testing) 3.6.4 Biological testing

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

HY Laboratories Ltd. is a contract laboratory that performs the following QC tests of medicinal products and active substances for other parties:

Microbiology Testing

- Microbiological examination of non-sterile products
- Microbiological examination of sterile products
- Rapid Sterility Tests by the Bact/ALERT
- Bacterial Endotoxins test
- Verification of Spore Population in Biological Indicators
- Antimicrobial Effectiveness Testing
- Identification of Bacterial Isolates
- Mycoplasma detection (Broth/Agar Culture)
- Tests for environmental monitoring: determination of a population of microorganisms on surfaces and in the air.

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

20 -12- 2021

Molecular Biology Testing

- Identification of micro-organisms by PCR and Sequencing
- Mycoplasma detection by PCR
- Sequencing of DNA with Genetic Analyzer
- Residual DNA Testing by qPCR
- Gene copy number / Bio-Distribution / Microorganism nucleic acid quantitation using Real Time PCR
- Gene expression number using Real Time PCR

Physical/ Chemical testing

- by ICP-MS (Inductively Coupled Plasma Mass Spectrometry)

The Institute for Standardization and Control of Pharmaceuticals
Pharmaceutical Administration, Ministry of Health
9 Ya'akov Eli'av St., Jerusalem 9546208, Israel
Tel: +972-2-6551717 Fax: +972-2-6551777

וכון לביקורת ותקנים של חומרי רפואה
ף הרוקחות, משרד הבריאות
וב יעקב אליאב 9, ירושלים 9546208
02-6551777 פקס: 02-6551717

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

Michael Carmi, Pharmacist, GMP inspector

e-mail: michael.carmi@moh.gov.il
phone: office 972 -2-6551795, cell 972-50-6242452

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

20 -12- 2021

The Institute for Standardization and Control of Pharmaceuticals
Pharmaceutical Administration, Ministry of Health
9 Ya'akov Eli'av St., Jerusalem 9546208, Israel
Tel: +972-2-6551717 Fax: +972-2-6551777

וכון לביקורת ותקנים של חומרי רפואה
ף הרוקחות, משרד הבריאות
וב יעקב אליאב 9, ירושלים 9546208
02-6551777 פקס: 02-6551717