



Certificate No: **GMP 136/6**

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 HY LABORTORIES LTD.

Site address 6 MENACHEM PLAUT ST., TAMAR PARK, REHOVOT, ISRAEL

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

and

Is a contract laboratory, performing Microbiology Testing & Molecular Biology Testing for other parties

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **4, 5 and 8 May 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 **two years** have elapsed since the date of that inspection (July 2014). 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

Part 2

Human Medicinal Products

Veterinary Medicinal Products

Human Investigational Medicinal Products

1. MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

1.6 Quality control testing

1.6.1 Microbiology: sterility

1.6.2 Microbiology: non-sterility

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

3.6 Quality Control Testing

3.6.3 Microbiological testing (including sterility testing)

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

HY LABORTORIES LTD. is a contract laboratory that performs the following QC tests:

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 air

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 using Real Time PCR



- Gene expression number using Real Time PCR
- Physical/ Chemical testing
- by ICP-MS (Inductively Coupled Plasma Mass Spectrometry) of products/ raw materials including APIs

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

Rachel, Shimonovitz - GMP Head of Inspectorate

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