Certificate No: **GMP 36/5**

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	**MEDISON PHARMA LTD.** **10 HaShiloach St., Petach Tikva, Israel**
Site address	**20 HaMagshimim St., Petach Tikva, Israel**

Has been inspected under the Israeli inspection programme in connection with manufacturing authorization no. **MIA 36** in accordance with the above mentioned laws and regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **18-19 July 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 **five 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
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משרד הבריאות
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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

1.5 Packaging only *(of imported medicinal products)*

1.5.2 Secondary packing

- *relabeling of primary containers (glass containers only)*
- *customization (secondary relabeling and leaflets adding/replacing)*

2 IMPORTATION OF MEDICINAL PRODUCTS

2.2 Batch certification of imported medicinal products

2.2.1 Sterile Products

2.2.1.1 Aseptically prepared

2.2.1.2 Terminally sterilized

2.2.2 Non-sterile products

2.2.3 Biological medicinal products

2.2.3.1 Blood products *(containing Albumin)*

2.2.3.2 Immunological products

2.2.3.5 Biotechnology products

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

The manufacturing (packaging) activities are performed on site and/or by a contract manufacturer

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

Michael Carmi, Pharmacist - GMP Inspector

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30 -04- 2019

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

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