Certificate No: **GMP 93/2**

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 **PROPHARM LTD**

Site address **23 BEN GURION AVENUE, ZICHRON YA'AKOV , ISRAEL**

Has been inspected under the Israeli inspection programme, in connection with manufacturing authorization no. **MIA 93**, 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 **29 August 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 after **28 February 2018**. 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
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Part 2

HUMAN MEDICINAL PRODUCTS

MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

1.5 Packaging

1.5.2 Secondary packing :*Customization only ; performed by a contract manufacturer*

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

2.3 Other importation activities

2.3.1 Site of physical importation : *site of the contract manufacturer*

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

- The site is an administrative release site (QA/QP activities) of a local importer
- The storing and distributing of the imported medicinal products are performed 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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03-10-2017

MINISTRY OF HEALTH, JERUSALEM
Gov. Institute for Control & Standard of Pharmaceuticals

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