Certificate No : **GMP 44/3**

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	**Concept For Pharmacy Ltd.** **POB 2105, Kfar Saba, Israel**
Site address	**21 Atir Yeda St., Ind. Zone, Kfar Saba, Israel**

Has been inspected under the Israeli inspection programme, in connection with manufacturing authorization no. **MIA 44,** 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 **23-24 January 2018**, 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. 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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Part 2

HUMAN MEDICINAL PRODUCTS

1 MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

1.5 Packaging only *(of imported medicinal products)*

1.5.2 Secondary packing *(limited to customization)*

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

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

None

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

Michael Carmi, Pharmacist, GMP Inspector

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

13 -03- 2018

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