משרד הבריאות

לחיים בריאים יותר

המינהל לטכנולוגיות רפואיות ותשתיות אגף הרוקחות, המכון לביקורת ותקנים של חומרי רפואה

The Institute for Standardization and Control of Pharmaceuticals

Certificate No: GMP 39.3

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

FISCHER PHARMACEUTICAL INDUSTRIES LTD.

Site address
9 BAR YOCHAI ST., BNEI BRAK, ISRAEL

Has been inspected under the Israeli inspection programme in connection with manufacturing authorization no. MIA 39 in accordance with the above mentioned laws and regulations

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From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **1719- JUNE 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 **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 - Pharmaceutical Administration
The Institute for Standardization and Control of Pharmaceuticals
P.O.B 34410 Jerusalem 9134302
Tel: 02-6551717 Fax: 02-6551777

משרד הבריאות - אגף הרוקחות
המכון לביקורת ותקנים של חומרי רפואה
ת.ד. 34410 ירושלים 9134302
טל: 02-6551717 פקס: 02-6551777

משרד הבריאות

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

1.1 **Sterile products**

1.1.1 Aseptically prepared

1.1.1.4 Small volume liquids : Eye Drops

1.1.3 Batch certification

1.6 **Quality control testing**

1.6.1 Microbiological: sterility

1.6.2 Microbiological: non-sterility

1.6.3 Chemical/Physical

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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Fax: 972-2-6551781

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

01-07-2018