מדינת ישראל
STATE OF ISRAEL

MINISTRY OF HEALTH
PHARMACEUTICAL ADMINISTRATION
THE INSTITUTE FOR STANDARDIZATION
AND CONTROL OF PHARMACEUTICALS

משרד הבריאות
אגף הרוקחות
המכון לבקורת ולתקנים של חומרי רפואה

Certificate No:

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

Site address
T

Has been inspected under the Israeli inspection programme, ~~in connection with manufacturing authorisation no~~. **(not relevant for APIs manufacturers)**, in accordance with the above mentioned laws and regulations

and

Is an active substance manufacturer that has been inspected in accordance with the above mentioned laws and regulations and ICH Q7

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on , 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

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Part 2

3 MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance(s):

3.1 Manufacture of Active Substance by Chemical Synthesis

3.5 General Finishing Steps

3.5.1 Physical processing steps, specify: *drying, milling/micronisation, sieving*

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing):

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

please see above

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

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