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המכון לנאמנות ופיקוח תרופות והשיתוף
מכון לביקורת ותקינים של תרופות רפואה
The Institute for Standardization and Control of Pharmaceuticals

Confirmation No.

**Written Confirmation For Exported Active Substances
For Medicinal Products For Human Use**

In accordance with the Israeli Pharmaceutical Legislation, ICH Q7 and PIC/S GMP

This confirmation regards the manufacturer

At its manufacturing plant

And regarding the following listed Active Substance(s), manufactured at the above mentioned site, and which are or may be sold and distributed locally and exported for medicinal products for human use:

Active Substance	Activity

1. The standards of Good Manufacturing Practice applicable to this manufacturing site are at least equivalent to those laid down in the Israeli Pharmaceutical Legislation, ICH Q7 and PIC/S GMP.
2. The manufacturing site is subject to regular controls and to the effective enforcement of Good Manufacturing Practice, including repeated inspections, so as to ensure a protection of public health at least equivalent to that in the Israeli Pharmaceutical Legislation, ICH Q7 & PIC/S GMP.

The authenticity of this written confirmation may be verified with the ISCP.

Address of issuing regulatory authority:

Name and function of Responsible Person:

E-mail, Telephone no., and fax no.:

e-mail:

tel-office:

Signature (handwritten)

Stamp of the authority (original) and date



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משרד
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