Certificate No: **GMP 178/2**

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 **IMI TAMI Institute for R&D Ltd. "QC Pharma" Laboratory**

Site address **Deshanim Road, Kiryat Ata Ind. Zone, Israel**

Has been inspected under the Israeli inspection programme, in accordance with the above mentioned laws and regulations

and

Has been inspected as a contract laboratory, that performs testing of pharmaceuticals for other parties

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **27-28 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 EudraGMDP. If it does not appear, please contact the issuing authority.

(*) these requirements fulfill the GMP recommendations of WHO

The Institute for Standardization And Control of Pharmaceuticals
Pharmaceutical Administration
MTIR Division, Ministry of Health
9 Ya'akov Eli'av St., Giv'at Sha'ul, Jerusalem
P.O.B 34410 Jerusalem 9134302
Tel: +972-2-6551717 Fax: +972-2-6551777

המכון לביקורת ותקנים של חומרי רפואה
אגף הרוקחות
חטיבת טכנולוגיות רפואיות, מידע ומחקר
משרד הבריאות
רחוב יעקב אליאב 9, גבעת שאול, ירושלים
ת.ד. 34410, ירושלים 9134302
טל: 02-6551717 פקס: 02-6551777

Part 2

1. MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS 1.6 Quality control testing 1.6.3 Chemical/Physical
3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES 3.6 Quality control testing 3.6.1 Physical / Chemical testing

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

Several laboratories are located on site. However, this certificate pertains only to the "QC Pharma" laboratory, that performs chemical/physical testing of Pharmaceuticals for other parties.

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

Rina Heimlich, GMP Inspector

Email: rina.heimlich@moh.gov.il
Phone: office 972 -2-6551794, cell 972-50-6242472
Fax: 972-2-6551781

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

27 -08- 2018

The Institute for Standardization And Control of Pharmaceuticals
Pharmaceutical Administration
MTIR Division, Ministry of Health
9 Ya'akov Eli'av St., Giv'at Sha'ul, Jerusalem
P.O.B 34410 Jerusalem 9134302
Tel: +972-2-6551717 Fax: +972-2-6551777

המכון לביקורת ותקנים של חומרי רפואה
אגף הרוקחות
חטיבת טכנולוגיות רפואיות, מידע ומחקר
משרד הבריאות
רחוב יעקב אליאב 9, גבעת שאול, ירושלים
ת.ד. 34410, ירושלים 9134302
טל: 02-6551717 פקס: 02-6551777