Certificate No: **GMP 267/1**

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 **Puterman Enterprising, Management and Distribution Ltd. (Ex Lab)**

Site address **3 Pinchas Sapir St., Weizmann Science Park, Ness Ziona, 7403626 ,Israel**

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

and

And has been inspected as a contract manufacturer that offers holding of stability samples for other parties

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **12 December 2022**, 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 JERUSALEM
GOV. INSTITUTE FOR CONTROL AND STANDARD OF PHARMACEUTICALS
משרד הבריאות

26 -01- 2023

מיכאל כרמי
ע. מפקח ארצי
תנאי יצור נאותים

The Institute for Standardization and Control of Pharmaceuticals
Pharmaceutical Administration, Ministry of Health
9 Ya'akov Eli'av St., Jerusalem, 9546208, Israel
Tel: + 972-2-6551717 , Fax: +972-2-6551777

המכון לביקורת ותקנים של חומרי רפואה
אגף הרוקחות, משרד הבריאות
רחוב יעקב אליאב 9, ירושלים 9546208
טל: 02-6551717 , פקס: 02-6551777

Part 2

Human Medicinal Products
Veterinary Medicinal Products
Human Investigational Medicinal Products

1. MANUFACTURING OPERATIONS

1.4 Other products or processing activity

1.4.3 Other: Holding of stability samples

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

The manufacturer is a contract manufacturer that offers holding of stability samples for other parties

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

Michael Carmi, Pharmacist, GMP Inspector

Email: michael.carmi@moh.gov.il
Phone: office 972 -2-6551795, cell 972-50-6242452

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

26 -01- 2023

מיכאל כרמי
ע. מפקח ארצי
תגאי יצור גאותים

The Institute for Standardization and Control of Pharmaceuticals
Pharmaceutical Administration, Ministry of Health
9 Ya'akov Eli'av St., Jerusalem, 9546208, Israel
Tel: + 972-2-6551717 , Fax: +972-2-6551777

המכון לביקורת ותקנים של חומרי רפואה
אגף הרוקחות, משרד הבריאות
רחוב יעקב אליאב 9, ירושלים 9546208
טל: 02-6551717 , פקס: 02-6551777