Certificate No : **GMP 230/6**

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

Isotopia Molecular Imaging Ltd.

Site address

Soreq Nuclear Research Center, Yavne, 81800, Israel

Has been inspected under the Israeli inspection programme, in connection with manufacturing authorization **MIA 230**, in accordance with the above mentioned laws and regulations

From the knowledge gained during inspection of this manufacturer, the latest of which were conducted on **19-22 April 2021,** 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

02 -08- 2021

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

The Institute for Standardization and Control of Pharmaceuticals
Pharmaceutical Administration , Ministry of Health
9 Ya'akov Eli'av St., Jerusalem 9546208 , Israel
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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

1. MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

1.1 Sterile products

1.1.1 Aseptically prepared

1.1.1.2 Lyophilizates

1.1.1.4 Small volume liquids

1.1.1.6 Other aseptically prepared products

1.1.2 Terminally sterilized

1.1.2.3 Small volume liquids

1.1.3 Batch certification

1.5 Packaging

1.5.1 Primary packing

1.5.1 Primary packing

1.6 Quality control testing

1.6.1 Microbiological: sterility

1.6.2 Microbiological: non-sterility

1.6.3 Chemical/Physical

1.6.4 Biological

Any restrictions or clarifying remarks related to the medicinal products

None

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3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance(s):

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other <free text> *Lyophilization of active substance*
(see restrictions or clarifying remarks section, below)

Any restrictions or clarifying remarks related to the APIs

The lyophilization is performed for another firm, a manufacturer of APIs, under contractual agreement.

Part 2

HUMAN INVESTIGATIONAL MEDICINAL PRODUCTS

1. MANUFACTURING OPERATIONS – INVESTIGATIONAL MEDICINAL PRODUCTS

1.1 Sterile products

1.1.1 Aseptically prepared

1.1.1.2 Lyophilizates

1.1.1.4 Small volume liquids

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Any restrictions or clarifying remarks related to the investigational medicinal products :

The following investigational medicinal products are manufactured on site:

- **PSMA-11, injection : cold kit for the preparation of Ga68**
  This product is a lyophilized product, developed by Isotopia Molecular Imaging Ltd.
- **LC-101, liposomal injection of Doxorubicin HCl 2mg/ml**
  This cytotoxic product is manufactured in campaigns, by using dedicated and/or disposable pieces of equipment. The product's sanitation and cleaning methods were validated.
- **UGN-102, 60ml gel (inert vehicle for drugs)**
  This product is manufactured under contractual agreement for Urogen Pharma Ltd.

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

The main activity on site is the manufacturing of sterile medicinal products, by using aseptic process and terminal sterilization.

The plant also performs lyophilization of active substance, under contractual agreement for another firm (a manufacturer of APIs).

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

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