Certificate No : **GMP 230/9**

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 no. **MIA 230**, in accordance with the above mentioned laws and regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **18-22 February 2024**, 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
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משרד הבריאות

מיכאל כרמי
ע. מפקח ארצי
תנאי יצור נאותים

01-04-2024

The Institute for Standardization and Control of Pharmaceuticals
Pharmaceutical Administration, Ministry of Health
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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

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<u>Any restrictions or clarifying remarks related to the medicinal products</u>

None

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Part 2

HUMAN INVESTIGATIONAL MEDICINAL PRODUCTS

1. MANUFACTURING OPERATIONS – INVESTIGATIONAL MEDICINAL PRODUCTS

For Phase III Clinical Trials

1.1 Sterile products

1.1.1 Aseptically prepared

1.1.1.2 Lyophilizates

1.1.1.4 Small volume liquids

Any restrictions or clarifying remarks related to the investigational medicinal products for Phase II Clinical Trials:

The following investigational medicinal products are manufactured on site:

●UGN-102, 60ml gel (inert vehicle for drugs)
This product is manufactured under a contractual agreement with Urogen Pharma Ltd

●ELGN-2112, oral formulation of recombinant human insulin under clinical development to stimulate the development of extremely low gestational age newborns (born more than 3 months before term).
This product is manufactured under a contractual agreement with Elgan Pharma Ltd

Investigational products are not included in the ACAA between the EU and Israel

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3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

3.1 Manufacture of active substances by chemical synthesis

3.1.4 Other *Lyophilization of active substances (under contractual agreements with other parties)*

Any restrictions or clarifying remarks related to the active substances

The plant is authorized to perform lyophilization of active substance and inert matrixes (vehicles) as a contract agent of other parties

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

The main activity on site is the manufacture of sterile medicinal products, by aseptic processing and terminal sterilization.

The plant is also authorized to perform lyophilization of active substance and inert matrixes (vehicles) as a contract agent of other parties.

Investigational products (IMPs)are not included in the ACAA between the EU and Israel

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

Michael Carmi, Pharmacist, GMP Inspector

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