Certificate No : **GMP 230/1**

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	**Isotopia Molecular Imaging Ltd.**
Site address	**Soreq Nuclear Research Center, Yavne, 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 **17-20 February 2019** 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

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המכון לביקורת ותקנים של חומרי רפואה
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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

1.5.2 Secondary 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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Part 2

HUMAN INVESTIGATIONAL MEDICINAL PRODUCTS
1. MANUFACTURING OPERATIONS – INVESTIGATIONAL MEDICINAL PRODUCTS
1.1 Sterile products
1.1.1 Aseptically prepared
1.1.1.4 Small volume liquids

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

The following investigational medicinal products are manufactured on site:

- ***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.

- ***TC-3, UG-1,** gel for injection (inert vehicle for drugs)*
  This product is manufactured under contractual agreement, for Urogen Pharma Ltd.

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

The effective date of this certificate is 1 April 2019.

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

25 -03- 2019

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