



אישור יצרן / יבואן תכשירים רפואיים MANUFACTURER'S / IMPORTER'S AUTHORIZATION

Authorization number	מספר האישור
MIA 230/2024/A	
Name of authorization holder	שם בעל האישור
Isotopia Molecular Imaging Ltd.	איזוטופיה מולקולר אימג'ינג בע"מ
Address of site	כתובת האתר
Soreq Nuclear Research Center Yavne, 81800, Israel	המרכז למחקר גרעיני שורק יבנה 81800
Legally registered address of authorization holder	כתובת בעל האישור
As written above	ברשום לעיל
Scope of authorization and dosage forms	תחומי האישור וצורות המינון
See Annexes 1, 2	ראה נספחים 1, 2
Legal basis of authorization	הבסיס החוקי לאישור
Pharmacist Regulations [Good Manufacturing Practice] 2008	תקנות הרוקחים [תנאי ייצור נאותים] תשס"ח
Responsible officer of Israeli Ministry Of Health granting the authorization	בעל התפקיד ברשות האחראי למתן האישור
Michael Carmi, Pharmacist GMP inspector	מיכאל כרמי, רוקח יכז ארצי בקרת מפעלים
Signature, stamp and date	חתימה, חותמת ותאריך
Email: michael.carmi@moh.gov.il Phone: office 972-2-6551795 cell 972-50-6242452	 מיכאל כרמי ע. מפקח ארצי תנאי ייצור נאותים 13-03-2024



SCOPE OF AUTHORIZATION

ANNEX 1 – MEDICINAL PRODUCTS

Name and address of the site **Isotopia Molecular Imaging Ltd.**
Soreq Nuclear Research Center, Yavne, 81800, Israel

<input checked="" type="checkbox"/> Human Medicinal Products	
AUTHORIZED OPERATIONS	
<input checked="" type="checkbox"/> Manufacturing Operations (according to part 1)	
Part 1 - MANUFACTURING OPERATIONS	
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
1.4	Other products or manufacturing activity
	1.4.1 Manufacture of: 1.4.1.3 other: Lyophilization of active substances <i>(under contractual agreements with other parties)</i>
1.5	Packaging
	1.5.1 Primary packing
	1.5.2 Secondary packing
1.6	Quality control testing

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	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 scope of the medicinal products

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.

13-03-2024

מיכאל כרמי
ע. מפקח ארצי
תנאי יצור נאותים

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



SCOPE OF AUTHORIZATION

ANNEX 2 - INVESTIGATIONAL MEDICINAL PRODUCTS

Name and address of the site **Isotopia Molecular Imaging Ltd.**
Soreq Nuclear Research Center, Yavne, 81800, Israel

1.

1. MANUFACTURING OPERATIONS OF INVESTIGATIONAL PRODUCTS **For Phase III Clinical Trials**

1.1 Sterile products

1.1.1 Aseptically prepared

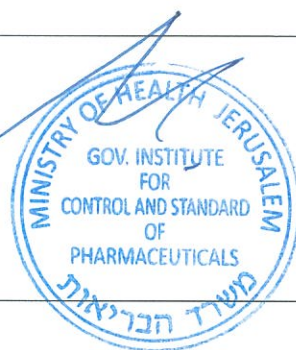
1.1.1.2 Lyophilizates

1.1.1.4 Small volume liquids

1.1.3 Batch certification

13-03-2024

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

The following investigational medicinal products are manufactured on site:

- PSMA-11, injection: cold kit for the preparation of Ga68-PSMA-11
This product is a lyophilized product, developed by Isotopia Molecular Imaging Ltd.
- 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