



NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY

Directorate for Drug Inspection

National Centre For Public Health And Pharmacy

CERTIFICATE NUMBER: *NNGYK/73240-6/2025*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1,2}

Part 1

Issued following an inspection in accordance with
Art. 15 of Directive 2001/20/EC as amended
Art. 111(5) of Directive 2001/83/EC as amended
The competent authority of Hungary confirms the following:
The manufacturer: *Institute of Isotopes Co. Ltd.*
Site address: *Konkoly-Thege Miklos Ut 29-33, Budapest Xii, 1121, Hungary*
OMS Organisation Id. / OMS Location Id.: *ORG-100010647 / LOC-100016844*
Has been inspected under the national inspection programme in connection with manufacturing
authorisation no. *HU-M-IZOT* in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive
2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted
on *2025-05-06*, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.³

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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>). 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 EudraGMDP. If it does not appear, please contact the issuing authority.

¹The certificate referred to in paragraph Art. 15 of Directive 2001/20/EC and Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products	
Human Investigational Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids Special Requirements 5 Radiopharmaceuticals 1.1.1.6 Other: Kits for radiolabelling & Aseptically prepared radionuclide generators(en) Special Requirements 5 Radiopharmaceuticals
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids Special Requirements 5 Radiopharmaceuticals 1.1.2.5 Other: Kits for radiolabelling(en) Special Requirements 5 Radiopharmaceuticals
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell Special Requirements 5 Radiopharmaceuticals 1.2.1.10 Radionuclide generators Special Requirements 5 Radiopharmaceuticals
	<i>1.2.2 Batch certification</i>

1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell Special Requirements 5 Radiopharmaceuticals 1.5.1.10 Radionuclide generators Special Requirements 5 Radiopharmaceuticals
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.1 Microbiological: sterility</i> <i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	<i>2.2.2 Non-sterile products</i>
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>
	<i>2.3.2 Importation of intermediate which undergoes further processing</i>

Any restrictions related to the scope of this certificate:

Clarifying remarks (for registered users)

The validity of the GMP Certificate is one year. Based on the for cause inspection (02.10.2025) related to quality defect product recall.

Clarifying remarks (for public users)

The validity of the GMP Certificate is one year.

2025-10-07

Name and signature of the authorised person of the
Competent Authority of Hungary



Andras Mittner
National Centre For Public Health And Pharmacy

Tel:
Fax:

