



*National Institute for Quality- and Organizational Development in
Healthcare and Medicines*

CERTIFICATE NUMBER: *OGYI/3233-7/2012***CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER****Part 1**

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Hungary confirms the following:

The manufacturer: *Izotóp Intézet Kft./Institute of Isotopes Co. Ltd.*

Site address: *Konkoly Thege M. u. 29-33., Budapest, 1121, Hungary*

Has been inspected under the national inspection programme in connection with manufacturing
authorisation no. *OGYI/48145-2/2010* in accordance with Art. 40 of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on
2012-02-01 , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC

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, after which time the issuing authority should be consulted. This certificate is valid only
when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified with
the issuing authority.

Part 2

Human Medicinal Products

1 Manufacturing Operations

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up,
packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the
contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under
the relevant items;

- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing
penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potential hazardous active
ingredients this should be stated under the relevant produce type and dosage form;