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Certificate No.: OGYI/.....25317-2...../2011

Importing (requesting) country: Italy

CERTIFICATE OF GMP COMPLIANCE

(MEDICINAL PRODUCT MANUFACTURER AUTHORIZED IN HUNGARY)

Part 1

Issued in accordance with Art. 111 of Directive 2001/83/EC

The competent authority of *Hungary* confirms the following:

The manufacturer: ***Biropharma Első Magyar Biotechnológiai Kft.***

Site address: ***6413 Kunfehértó, IV. körzet 6.***

has been inspected under the national inspection program in connection with manufacturing authorization no: ***15040/47/2008*** in accordance with Art. 40 of *Directive 2001/83/EC* transposed in the following national legislation:

The *Act XCV of 2005 on medicinal products for human use* and *Decree of Ministry of Health No. 44/2005 (X.19.) regulating personal and materials conditions for the manufacture of medicinal products.*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***01. and 02. June 2011.*** it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC, the Agreement of Mutual Recognition between the European Community and MRA partners and GMP recommendations of WHO.

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. The authenticity of this certificate may be verified with the issuing authority.

Name and signature of the authorized person of the Competent Authority of *Hungary*:


Dr. Krisztina Török
Director General

Date: 15 June 2011

Part 2

1 Manufacturing operation(s)

Human Medicinal Products Human Investigational Medicinal Products

1.1 Sterile products

Aseptically prepared

Terminally sterilized

Batch certification only

1.2 Non-sterile products

Dosage forms: Liquids dosage forms for internal use

Solutions, Oral drops, Herbal extracts

Batch certification only

1.3 Biological medicinal products

Dosage forms:

Batch certification only

1.4 Other products or manufacturing activity

Formulations/activity:

Batch certification only

1.5 Packaging only

Primary packaging. Dosage forms:

Secondary packaging

1.6 Quality Control Testing

Microbiological: sterility

Microbiological: non-sterility

Chemical/Physical

Biological

Name and signature of the authorized person of the Competent Authority of *Hungary*:

Date: 15 June 2011


Dr. Krisztina Török
Director General


Certificate No.: OGYI/.....25317-2...../2011

2 Importation of medicinal products

2.1 Quality Control Testing

Microbiological: sterility

Microbiological: non-sterility

Chemical/Physical

Biological

2.2 Batch certification of imported medicinal products

Sterile

Non-sterile

Biological

Other:

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

Name and signature of the authorized person of the Competent Authority of *Hungary*:

Date: 15 June 2011


Dr. Krisztina Török
Director General

