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

CERTIFICATE NUMBER: ***OGYI/39300-6/2012***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with :

The competent authority of Hungary confirms the following:
The manufacturer: ***REANAL Finomvegyszergyár Zrt. /Reanal Private Co Ltd.***
Site address: ***Telepes utca 53., Budapest, 1147, Hungary***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***OGYI/6440-4/2010*** 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 ***2012-10-11*** , it is considered that it complies with :

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

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;

1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2013-01-23

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

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

CERTIFICATE NUMBER: ***OGYI/39300-7/2012***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with :

The competent authority of Hungary confirms the following:
The manufacturer: ***REANAL Finomvegyszergyár Zrt. /Reanal Private Co Ltd.***
Site address: ***Telepes utca 54-56., Budapest, 1147, Hungary***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***OGYI/6440-4/2010*** 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 ***2012-10-11*** , it is considered that it complies with :

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

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;

1.2	**Non-sterile products**
	1.2.1 Non-sterile products (list of dosage forms) 1.2.1.11 Semi-solids Special Requirements 9 Other: Ointment(en)
1.4	**Other products or manufacturing activity** (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc).
	1.4.1 Manufacture of 1.4.1.4 Other: Primary packaging only(en) Special Requirements 9 Other: Alcoholum 96%(en)
1.5	**Packaging only**
	1.5.2 Secondary packing

2013-01-23

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

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