



*National Institute of Pharmacy and Nutrition*

CERTIFICATE NUMBER: *OGYÉI/7594-6/2018*

**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  
Art. 15 of Directive 2001/20/EC

The competent authority of Hungary confirms the following:

The manufacturer: *PANNONPHARMA Gyógyszergyártó Korlátolt Felelősségű Társaság  
(PANNONPHARMA Gyógyszergyártó Kft.) Pannonpharma Ltd.*

Site address: *Pannonpharma út 1., Pécsvárad, 7720, Hungary*

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. *HU-M-PANN* in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on *2018-02-22* , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC<sup>3</sup>

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. 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.

<sup>1</sup> The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> These requirements fulfil the GMP recommendations of WHO.

## Part 2

Human Medicinal Products  
Human Investigational Medicinal Products

### 1 MANUFACTURING OPERATIONS

#### 1.1 Sterile products

*1.1.3 Batch certification*

#### 1.2 Non-sterile products

*1.2.1 Non-sterile products (processing operations for the following dosage forms)*

1.2.1.1 Capsules, hard shell

1.2.1.5 Liquids for external use

Special Requirements

7 Other: Batch certification only(en)

1.2.1.6 Liquids for internal use

Special Requirements

7 Other: Batch certification only(en)

1.2.1.8 Other solid dosage forms: Powders and granules(en)

1.2.1.11 Semi-solids

Special Requirements

7 Other: Batch certification only(en)

1.2.1.13 Tablets

*1.2.2 Batch certification*

#### 1.5 Packaging

*1.5.1 Primary Packing*

1.5.1.1 Capsules, hard shell

1.5.1.8 Other solid dosage forms: Powders and granules(en)

1.5.1.13 Tablets

Special Requirements

7 Other: Including products for hormonal activity.(en)

*1.5.2 Secondary packing*

#### 1.6 Quality control testing

*1.6.2 Microbiological: non-sterility*

*1.6.3 Chemical/Physical*

*1.6.4 Biological*



<b>2 IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	2.1.2 <i>Microbiological: non-sterility</i> 2.1.3 <i>Chemical/Physical</i> 2.1.4 <i>Biological</i>
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	2.2.1 <i>Sterile products</i> 2.2.1.1 <i>Aseptically prepared</i> 2.2.1.2 <i>Terminally sterilised</i>
	2.2.2 <i>Non-sterile products</i>
<b>2.3</b>	<b>Other importation activities</b>
	2.3.1 <i>Site of physical importation</i>
	2.3.2 <i>Importation of intermediate which undergoes further processing</i>

Any restrictions related to the scope of this certificate :

*Certificate includes Batch certification activity for Sterile products, Batch certification activity for Non Sterile products ( Liquids for external and internal use, Semi-Solids ) and Primary Packing of Tablets (including products with hormonal activity) for Human Medicinal Products only. Certificate includes Importation activity for Human Medicinal Products only. Certificate includes Manufacturing operations for Human Investigational Medicinal Products ( Liquids for external and internal use) only.*

Clarifying remarks (for public users)

*Certificate includes Batch certification activity for Sterile products, Batch certification activity for Non Sterile products ( Liquids for external and internal use, Semi-Solids ) and Primary Packing of Tablets (including products with hormonal activity) for Human Medicinal Products only. Certificate includes Importation activity for Human Medicinal Products only. Certificate includes Manufacturing operations for Human Investigational Medicinal Products ( Liquids for external and internal use) only.*

2018-05-14

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



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