



## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER/IMPORTER

### Part 1

Issued following an inspection in accordance with Art. 111 (5) of Directive 2001/83/EC the competent authority of Liechtenstein, Amt für Gesundheit, confirms the following:

**Phafag AG**  
**Gewerbeweg 12**  
**9486 Schaanwald**  
**Liechtenstein**

has been inspected in connection with the authorisation Nr. 6652\_01\_15/162 in accordance with Art. 40 of Directive 2001/83/EC, transposed in the following national legislation: Gesetz über den Verkehr mit Arzneimitteln sowie den Umgang mit menschlichen Geweben und Zellen im Europäischen Wirtschaftsraum, LR 812.103.

From the knowledge gained during inspection of this manufacturer/importer, which was conducted on 15 October 2015, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice<sup>1</sup> laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing/importing site at the time of 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 the mentioned inspection, after which 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.

<sup>1</sup> These requirements fulfill the GMP recommendations of WHO.

## CERTIFICATE OF GMP COMPLIANCE Part 2

### 1 MANUFACTURING OPERATIONS– MEDICINAL PRODUCTS

#### 1.1. Sterile products

##### 1.1.3 Batch certification of terminally sterilised liquids

#### 1.2. Non-sterile products

##### 1.2.2 Batch certification of non-sterile intermediates and finished solid medicinal products

### 2 IMPORTATION OF MEDICINAL PRODUCTS

#### 2.2. Batch certification of imported medicinal products

##### 2.2. 1. Sterile products

##### 2.2. 1. 2. Terminally sterilised liquids

##### 2.2.2 Non-sterile intermediates and finished solid medicinal products

AMT FÜR GESUNDHEIT

*Batliner*



Mag. Brigitte Batliner  
Amtsapothekerin

Vaduz, 29<sup>th</sup> February 2016

Cert.No: GMP Li/01/16