

## Medicines and Healthcare products Regulatory Agency

### CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

#### Part 1

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

The competent authority of the United Kingdom confirms the following:

The manufacturer	PHYTOVATION LIMITED
Site address	UNITS 8/9 ZONE 6 CIBYN INDUSTRIAL ESTATE CAERNARFON LL55 2BD UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12/12/2017, it is considered that it complies with the principles of GMP for active substances

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 only valid 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.



## Part 2

Human Medicinal Products

### 1. MANUFACTURING OPERATIONS

**1.1 Sterile products**

Not Authorised

**1.2 Non-sterile products**

Not Authorised

**1.3 Biological medicinal products**

Not Authorised

**1.4 Other products or manufacturing activity**

Not Authorised

**1.5 Packaging**

Not Authorised

**1.6 Quality control testing**

Not Authorised

### 2. IMPORTATION OF MEDICINAL PRODUCTS

**2.1 Quality control testing of imported medicinal products**

Not Authorised

**2.2 Batch certification of imported medicinal products**

Not Authorised

**2.3 Other importation activities**

Not Authorised



**SENNA**

**3. MANUFACTURING OPERATIONS**

- 3.1 Manufacture of Active Substance by Chemical Synthesis**  
Not Authorised
  
- 3.2 Processing Activities of Active Substance from Natural Sources**
  - 3.2.1 Plant Source      Extraction
  
- 3.3 Manufacture of Active Substance using Biological Processes**  
Not Authorised
  
- 3.4 Manufacture of sterile active substance**  
Not Authorised
  
- 3.5 General Finishing Steps**
  - 3.5.1 Physical Processing Steps  
Milling, sieving, blending, drying
  
- 3.6 Quality Control Testing**
  - 3.6.1 Physical / Chemical testing
  
- 4 Other Activities**  
Not Authorised

