CERTIFICATE No. GIF-IW-400/0174_01_02/04/219/16

Main Pharmaceutical Inspector

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC and Art. 80(5) of Directive 2001/82/EC with amendments.

Main Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

Phytopharm Klęka S.A.
Klęka 1, 63-040 Nowe Miasto nad Wartą, POLAND

site address

Phytopharm Klęka S.A.
Klęka 1, 63-040 Nowe Miasto nad Wartą, POLAND

is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 80(1) of Directive 2001/82/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2008, No. 45, item 271 with amendments) in connection with registration no **96/WTC0174/API/15**.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **31/05/-03/06/2016**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC, Directive 91/412/EEC and the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

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 EudraGMP. If it does not appear, please contact the issuing authority.

acting Main Pharmaceutical Inspector

Zbigniew Niewójt

date: 2016 -08- 16

Main Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Zbigniew Niewójt
Main Pharmaceutical Inspector

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Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

Aloes arborescens fresh leaf aqueous extract, Ribwort Plantain juice stabilized with ethanol, Fresh Southernwood herb extract, Silver Birch leaf juice stabilized with ethanol, Fresh Onion ethanolic liquid extract, Fresh St. John's wort herb extract, Fresh European Mistletoe herb extract, Purple Coneflower herb juice stabilized with ethanol, Fresh Horse Chestnut unripe fruit extract, Valerian fresh extract, Yarrow juice stabilized with ethanol, Fresh Melissa herb extract, Fresh Dandelion herb extract, Dandelion root juice stabilized with ethanol, Coltsfoot leaf juice stabilized with ethanol, Nettle juice stabilized with ethanol, Fresh pine shoots liquid extract, Chokeberry juice stabilised with ethanol, St. John's wort herb juice stabilized with ethanol, Fresh Hawthorn inflorescence extract, Burdock herb juice stabilized with ethanol, Fresh Oat herb extract.

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.1 Extraction of substance from plant source
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (filtration) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.4 Other** (quarantine, releasing, storage, distribution)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)
4	**OTHER ACTIVITIES - ACTIVE SUBSTANCES**
	4.1. Distribution

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

acting Main Pharmaceutical Inspector

Zbigniew Niewójt

date: 2016 -08- 16

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