

2024 -01- 1 8



CHIEF PHARMACEUTICAL INSPECTOR

ISF.405.6.2024.IP.1  
WTC/0174\_01\_02/10

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

## Part 1

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

**Chief 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 transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2022, item 2301) and Art. 51g Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2022, item 2301 as amended) in connection with the entry in the Register no **96/WTC0174/API/15**.

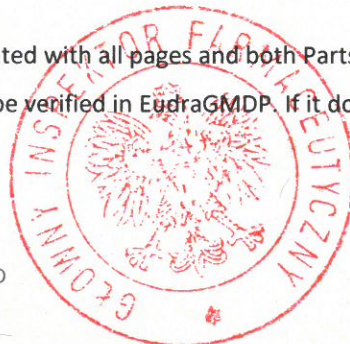
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **17-20/10/2023** it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive (EU) 2017/1572 and the principles of GMP for active substances referred to 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.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>).

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.

12 Senatorska str, 00-082 Warsaw, POLAND  
phone 22 635 99 51  
fax 22 635 99 57[www.gif.gov.pl](http://www.gif.gov.pl)  
[gif@gif.gov.pl](mailto:gif@gif.gov.pl)

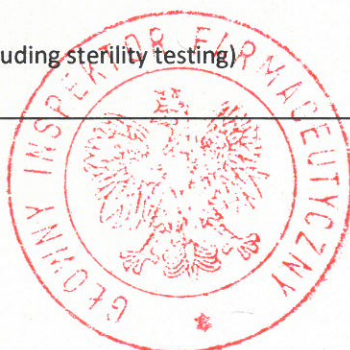
Part 2

**3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES**

**Active Substance(s):**

- Purple coneflower herb aqueous dry extract; Lime dry extract; Liquorice dry aqueous extract Devil's claw root dry extract

<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<b>3.2.1 Extraction of substance from plant source</b>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps (drying)</b></p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.3 Secondary Packaging</b> (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>



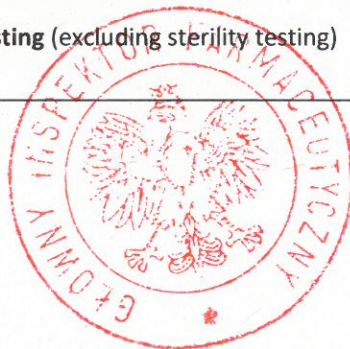
Part 2

**3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES**

**Active Substance(s):**

- **Melissa dry aqueous extract; Melissa leaf dry aqueous extract; Horse chestnut seed dry extract, Primula root dry extract; Ribwort plantain dry extract; Hop stabilite ethanolic – aqueous dry extract; Aloes dry extract, standardised**

<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<b>3.2.1 Extraction of substance from plant source</b>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps</b> (drying, milling, mixing)</p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.3 Secondary Packaging</b> (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>



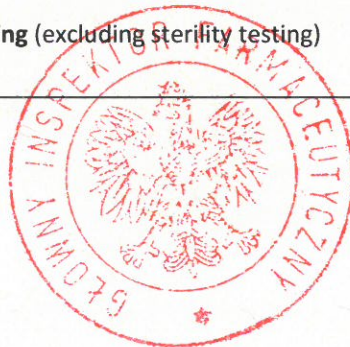
Part 2

**3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES**

Active Substance(s):

- Powdered aloes dried juice

<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<b>3.2.1 Extraction of substance from plant source</b>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps</b> (milling, mixing)</p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.3 Secondary Packaging</b> (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>

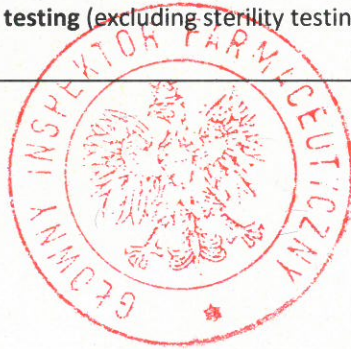


**3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES**

**Active Substance(s):**

- Purple Coneflower herb soft extract

<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<b>3.2.1 Extraction of substance from plant source</b>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps (concentration)</b></p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>



## Part 2

**3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES****Active Substance(s):**

- Coltsfoot leaf aqueous soft extract; Fresh Canadian horseweed herb soft extract; Thyme herb aqueous soft extract; Combined soft extract from: thyme herb, primula root

<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<b>3.2.1 Extraction of substance from plant source</b>
<b>3.5</b>	<b>General Finishing Steps</b>
	<b>3.5.1 Physical processing steps</b> (concentration, pasteurization)  <b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)  <b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)
<b>3.6</b>	<b>Quality Control Testing</b>
	<b>3.6.1 Physical / Chemical testing</b>  <b>3.6.2 Microbiological testing</b> (excluding sterility testing)



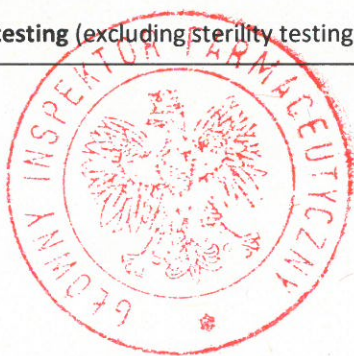
Part 2

**3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES**

Active Substance(s):

- Radish root dry extract

<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<p><b>3.2.5 Modification of extracted substance</b> (specify source 1)</p> <p><b>3.2.6 Purification of extracted substance</b> (specify source 1)</p>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps</b> (drying, milling)</p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.3 Secondary Packaging</b> (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>



**3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES**

**Active Substance(s):**

- Castor oil, virgin

<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps</b> (filtration)</p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>

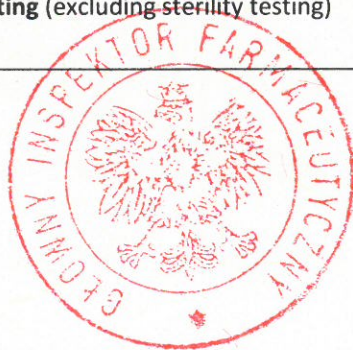




Part 2

<p><b>3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES</b></p> <p><b>Active Substance(s):</b></p> <ul style="list-style-type: none"> <li>- Hammamelis leaf and bark water distillate</li> </ul>
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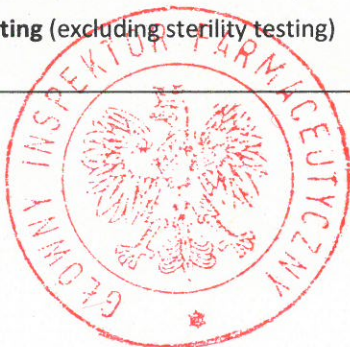
<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<p><b>3.2.1</b> Extraction of substance from plant source</p> <p><b>3.2.7</b> Other (steam distillation)</p>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1</b> Physical processing steps (filtration)</p> <p><b>3.5.2</b> Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.4</b> Other (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1</b> Physical / Chemical testing</p> <p><b>3.6.2</b> Microbiological testing (excluding sterility testing)</p>



Part 2

<p><b>3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES</b></p> <p>Active Substance(s):</p> <ul style="list-style-type: none"> <li>- Matricaria oil</li> </ul>	
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3.2	<p><b>Extraction of Active Substance from Natural Sources</b></p>
	<p><b>3.2.7 Other</b> (steam distillation)</p>
3.5	<p><b>General Finishing Steps</b></p>
	<p><b>3.5.1 Physical processing steps</b> (separation)</p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
3.6	<p><b>Quality Control Testing</b></p>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>

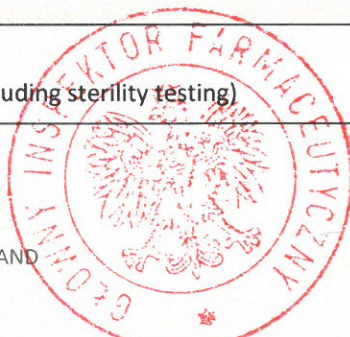


**3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES**

**Active Substance(s):**

Combined tincture from: goldenrod herb, common marigold flower, blessed thistle, rowan fruit, nettle leaf; Combined tincture from: common horse, chestnut flower, ginkgo leaf, common chamomile flower, common marigold flower; 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; 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 root juice stabilized with ethanol; Fresh oat herb extract; Anise tincture; Passion flower tincture; Goldenrod tincture; Motherwort tincture; Horsetail tincture; Hyssop tincture; Thyme tincture; Arnica tincture; Hop strobile tincture; St. John’s wort tincture; Hawthorn inflorescence tincture; Ginkgo tincture; Calendula tincture; Matricaria tincture; Sage tincture; Common soapwort tincture; Rose hip tincture; Artichoke leaf tincture; Lime tincture; Liquorice tincture; Lily-of-the valley herb tincture; Valerian tincture; Primula tincture; Peppermint tincture; Spring adonis tincture; Pelargonium sidoides tincture; Bitter tincture; Combined liquid extract from: elder flower, ribwort plantain leaf, thyme herb, primula flower, gentian root, liquorice root; Arnica herb tincture; Ribwort plantain leaf liquid extract; St. John’s wort liquid extract; Hawthorn fruit liquid extract; Valerian liquid extract; Melissa leaf liquid extract; Passion flower herb liquid extract; Primula root liquid extract; Tormentil liquid extract; Bitter-orange epicarp and mesocarp liquid extract; Rosemary leaf liquid extract; Thyme herb liquid extract; Senega root fluid extract; Cocillana liquid extract; Liquid combined extract of bearberry leaf, European goldenrod and nettle herb; Liquid combined extract of green bean pod, birch leaf, couch grass rhizome, blackberry leaf and rosehip ; Quillaia bark liquid extract; Cascara bark liquid extract; Hop strobile liquid extract; Artichoke herb liquid extract stabilized with ethanol; Elecampane root liquid extract; Iceland moss liquid extract; Combined liquid extract from: southernwood herb, milk thistle fruit, peppermint leaf, St. Benedict’s thistle herb, dandelion root, yarrow herb; Combined liquid extract from: matricaria flower, oak bark, sage leaf, arnica herb, calamus rhizome peppermint herb, thyme herb; Combined liquid extract from: oak bark, willow bark, sage herb, southernwood herb, thyme herb, yarrow herb; Pelargonium root tincture.

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

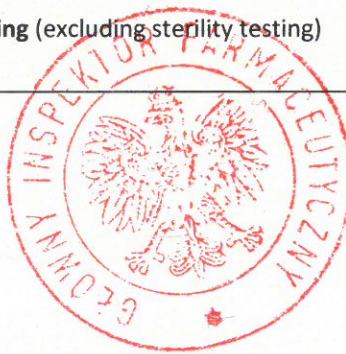


**3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES**

Active Substance(s):

- Matricaria liquid extract

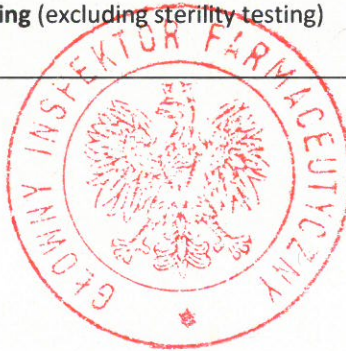
<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<b>3.2.1 Extraction of substance from plant source</b>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps</b> (filtration, homogenizing, mixing)</p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>



Part 2

<p><b>3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES</b></p> <p><b>Active Substance(s):</b></p> <ul style="list-style-type: none"> <li>- Calendula paraffin liquid extract</li> </ul>
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<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<b>3.2.1 Extraction of substance from plant source</b>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps</b> (pasteurization, homogenizing)</p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>



Part 2

**3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES**

**Active Substance(s):**

- Combined soft extract from: valerian root, melissa leaf, hop strobili, St. John’s wort herb, hawthorn inflorescence, passion flower herb, elder flower

<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<b>3.2.1 Extraction of substance from plant source</b>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps</b> (concentration, mixing)</p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>



<p><b>3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES</b></p> <p><b>Active Substance(s):</b></p> <ul style="list-style-type: none"> <li>- <b>Water extract from ribwort plantain’s leaves</b></li> </ul>	
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<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<b>3.2.1 Extraction of substance from plant source</b>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps</b> (homogenizing)</p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>



## Part 2

### 3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Milk thistle tincture

<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<b>3.2.5 Modification of extracted substance</b> (specify source 1)
<b>3.5</b>	<b>General Finishing Steps</b>
	<p><b>3.5.1 Physical processing steps</b> (filtration)</p> <p><b>3.5.2 Primary Packaging</b> (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p><b>3.5.4 Other</b> (quarantine, releasing, storage, distribution)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p><b>3.6.1 Physical / Chemical testing</b></p> <p><b>3.6.2 Microbiological testing</b> (excluding sterility testing)</p>

**Any restrictions or clarifying remarks related to the scope of this certificate:**

**This certificate should not be relied upon to reflect the compliance status if more than two years have elapsed since the date of the inspection.**



acting Chief Pharmaceutical Inspector

*Marcin Wójtowicz*  
**Marcin Wójtowicz**