

**Agency for medicinal products and medical devices of the Republic of  
Slovenia**

CERTIFICATE NUMBER: 401-2/2017-5

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**<sup>1, 2</sup>**Part 1**

Issued following an inspection in accordance with :

Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Slovenia confirms the following:

The manufacturer: **Vitiva, proizvodnja in storitve d.d.**

Site address: **Nova vas pri Markovcih 98, Markovci, 2281, Slovenia**

Has been inspected under the national inspection programme in accordance with Art. 40 of Directive 2001/83/EC .

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2017-02-10** , 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>
- The principles of GMP for active substances<sup>3</sup> 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 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

Manufacture of active substance. Names of substances subject to inspection :

**HELENIEN CONCENTRATE( en)**

**VALERIAN DRY HYDROALCOHOLIC EXTRACT( en)**

**HORSE CHESTNUT DRY EXTRACT( en)**

**BEARBERRY DRY EXTRACT( en)**

**MELISSA LEAF DRY EXTRACT( en)**

**PASSION FLOWER DRY EXTRACT( en)**

**HAWTHORN, DRY EXTRACT( en)**

**PEPPERMINT LEAF DRY EXTRACT( en)**

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : HELENIEN CONCENTRATE

#### 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 :  
drying, milling, sieving

3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

3.5.3 Secondary Packaging (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)

#### 3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

Active Substance : VALERIAN DRY HYDROALCOHOLIC 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 :  
drying, milling, sieving

3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

3.5.3 Secondary Packaging (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)

#### 3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

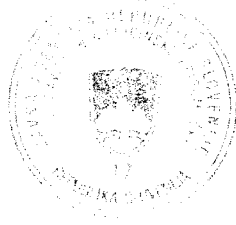
Active Substance : HORSE CHESTNUT DRY EXTRACT

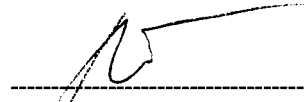
<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	3.2.1 Extraction of substance from plant source
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps : drying, milling, sieving
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.3 Secondary Packaging (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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing
Active Substance : BEARBERRY DRY EXTRACT	
<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	3.2.1 Extraction of substance from plant source
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps : drying, milling, sieving
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.3 Secondary Packaging (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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing
Active Substance : MELISSA LEAF DRY EXTRACT	
<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	3.2.1 Extraction of substance from plant source
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps : drying, milling, sieving
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.3 Secondary Packaging (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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing
Active Substance : PASSION FLOWER DRY EXTRACT	
<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>

	3.2.1 Extraction of substance from plant source
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps : drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing
Active Substance : HAWTHORN, DRY EXTRACT	
<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	3.2.1 Extraction of substance from plant source
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps : drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing
Active Substance : PEPPERMINT LEAF DRY EXTRACT	
<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	3.2.1 Extraction of substance from plant source
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps : drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing

2017-04-12

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



  
-----  
**Mr. Rok Martincic**  
**Agency for medicinal products and medical devices of**  
**the Republic of Slovenia**  
Tel: +386 8 2000641  
Fax: +386 8 2000510