

**Ministerium für Soziales, Gesundheit, Frauen und Familie**

CERTIFICATE NUMBER: **DE\_SL\_01\_GMP\_2019\_0001**

**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

Art. 80(5) of Directive 2001/82/EC as amended

Art. 15 of Directive 2001/20/EC

The competent authority of Germany confirms the following:

The manufacturer: **Ursapharm Arzneimittel GmbH**

Site address: **Industriestrasse 35, Saarbruecken, Saarland, 66129, Germany**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **DE\_SL\_01\_MIA\_2019\_0002** in accordance with Art. 40 of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2018-03-15** , 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 and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC<sup>3</sup>

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  
Veterinary Medicinal Products  
Human Investigational Medicinal Products

| <b>1 MANUFACTURING OPERATIONS</b> |                                                                                                                                                                                                                                                                                           |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1.1</b>                        | <b>Sterile products</b>                                                                                                                                                                                                                                                                   |
|                                   | <i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i><br>1.1.1.1 Large volume liquids<br>1.1.1.3 Semi-solids<br>1.1.1.4 Small volume liquids                                                                                                           |
|                                   | <i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i><br>1.1.2.3 Small volume liquids                                                                                                                                                                 |
| <b>1.2</b>                        | <b>Non-sterile products</b>                                                                                                                                                                                                                                                               |
|                                   | <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i><br>1.2.1.1 Capsules, hard shell<br>1.2.1.5 Liquids for external use<br>1.2.1.6 Liquids for internal use<br>1.2.1.11 Semi-solids<br>1.2.1.13 Tablets<br>1.2.1.17 Other: granular preparations(en) |
| <b>1.4</b>                        | <b>Other products or manufacturing activity</b>                                                                                                                                                                                                                                           |
|                                   | <i>1.4.1 Manufacture of</i><br>1.4.1.1 Herbal products<br>1.4.1.2 Homoeopathic products                                                                                                                                                                                                   |
|                                   | <i>1.4.2 Sterilisation of active substance/ excipients/ finished product</i><br>1.4.2.1 Filtration<br>1.4.2.2 Dry heat<br>1.4.2.3 Moist heat                                                                                                                                              |
| <b>1.5</b>                        | <b>Packaging</b>                                                                                                                                                                                                                                                                          |
|                                   | <i>1.5.1 Primary Packaging</i><br>1.5.1.8 Other solid dosage forms                                                                                                                                                                                                                        |
|                                   | <i>1.5.2 Secondary packaging</i>                                                                                                                                                                                                                                                          |

|                                            |                                                           |
|--------------------------------------------|-----------------------------------------------------------|
| <b>1.6</b>                                 | <b>Quality control testing</b>                            |
|                                            | 1.6.1 Microbiological: sterility                          |
|                                            | 1.6.2 Microbiological: non-sterility                      |
|                                            | 1.6.3 Chemical/Physical                                   |
| <b>2 IMPORTATION OF MEDICINAL PRODUCTS</b> |                                                           |
| <b>2.2</b>                                 | <b>Batch certification of imported medicinal products</b> |
|                                            | 2.2.1 Sterile products                                    |
|                                            | 2.2.1.1 Aseptically prepared                              |

Clarifying remarks (for public users)

**to 2.2: Import of bulkware (solutions for eye drops and nose sprays) for primary or secondary packaging**  
**Die Gueltigkeit des Zertifikates endet am 15.03.2021**

2019-01-18

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

-----  
**Confidential**  
**Ministerium für Soziales, Gesundheit, Frauen und**  
**Familie**  
 Tel: **Confidential**  
 Fax: **Confidential**