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# CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **A.Vogel AG, Grünaustrasse, 9325 Roggwil TG,** Authorisation No. 511618-102683939 with its site **A.Vogel AG, Grünaustrasse, 9325 Roggwil TG, Switzerland,** Site No. 1000497 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **11.11.2021** (dd.mm.yyyy).

| *No.* | *Operation* | *Scope** |
|---|---|---|
| **1** | **MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)** | |
| **1.2** | **Non-sterile products** | |
| 1.2.1 | Non-sterile products (processing operations for the following dosage forms) | |
| 1.2.1.1 | Capsules, hard shell | I |
| 1.2.1.5 | Liquids for external use | H/V, I |
| 1.2.1.6 | Liquids for internal use | H/V, I |
| 1.2.1.8 | Other solid dosage forms | H/V, I |
| 1.2.1.13 | Tablets | H/V, I |
| 1.2.2 | Batch certification (technical release) | H/V, I |
| **1.4** | **Other products or manufacturing activity** | |
| 1.4.1 | Manufacture of: | |
| 1.4.1.1 | Herbal products | H/V, I |
| 1.4.1.2 | Homoeopathic products | H/V, I |
| **1.5** | **Packaging** | |
| 1.5.1 | Primary packaging | |
| 1.5.1.1 | Capsules, hard shell | I |
| 1.5.1.2 | Capsules, soft shell | H/V, I |
| 1.5.1.5 | Liquids for external use | H/V, I |
| 1.5.1.6 | Liquids for internal use | H/V, I |
| 1.5.1.8 | Other solid dosage forms | H/V, I |
| 1.5.1.13 | Tablets | H/V, I |
| 1.5.2 | Secondary packaging | H/V, I |
| **1.6** | **Quality control testing** | |
| 1.6.3 | Chemical/Physical | H/V, I |



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| *No.* | *Operation* | *Scope** |
|---|---|---|
| **S.1.8** | **Blinding of medicinal products for clinical trials** | I |
| **3** | **MANUFACTURE OF ACTIVE SUBSTANCES** | |
| **3.2** | **Extraction of active substance from natural sources** | |
| 3.2.1 | Extraction of substance from plant source | H/V, I |
| **3.5** | **General finishing steps** | |
| 3.5.2 | Primary packaging | H/V, I |
| 3.5.3 | Secondary packaging | H/V, I |
| **3.6** | **Quality control testing** | |
| 3.6.1 | Physical / Chemical testing | H/V, I |

* Scope of authorisation:
H/V Human and veterinary medicinal products, without investigational products
V Veterinary medicinal products only, without investigational products
I Human investigational medicinal products
– Not specified

Berne, **31.10.2022** (dd.mm.yyyy)
**No. GMP-CH-1003691**

Swissmedic, Swiss Agency for Therapeutic Products

J. Büchi

Jacqueline Büchi

Swiss Agency for Therapeutic Products
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Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products



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