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# CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Apotheke Roter Ochsen AG , , 8750 Glarus,** Authorisation No. 511518-102613940 with its site **Apotheke Roter Ochsen AG Apotheke zum roten Ochsen, Vorstadt 50, 8200 Schaffhausen, Switzerland,** Site No. 1102858 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 **09.05.2019** (dd.mm.yyyy).

| *No.* | *Operation* | *Scope** |
|---|---|---|
| 1 | **MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)** | |
| **1.1** | **Sterile Products** | |
| 1.1.1 | Aseptically prepared (processing operations for the following dosage forms) | |
| 1.1.1.3 | Semi-solids | I |
| 1.1.1.4 | Small volume liquids | I |
| 1.1.2 | Terminally sterilised (processing operations for the following dosage forms) | |
| 1.1.2.3 | Small volume liquids | I |
| 1.1.3 | Batch certification (technical release) | I |
| **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 | I |
| 1.2.1.6 | Liquids for internal use | I |
| 1.2.1.8 | Other solid dosage forms | I |
| 1.2.1.11 | Semi-solids | I |
| 1.2.1.12 | Suppositories | I |
| 1.2.1.13 | Tablets | I |
| 1.2.2 | Batch certification (technical release) | I |
| **1.4** | **Other products or manufacturing activity** | |
| 1.4.1 | Manufacture of: | |
| 1.4.1.1 | Herbal products | I |
| **1.5** | **Packaging** | |
| 1.5.1 | Primary packing | |
| 1.5.1.1 | Capsules, hard shell | I |
| 1.5.1.5 | Liquids for external use | I |
| 1.5.1.6 | Liquids for internal use | I |



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| No. | Operation | Scope* |
|---|---|---|
| 1.5.1.8 | Other solid dosage forms | I |
| 1.5.1.11 | Semi-solids | I |
| 1.5.1.12 | Suppositories | I |
| 1.5.1.13 | Tablets | I |
| 1.5.2 | Secondary packing | I |
| **1.6** | **Quality control testing** | |
| 1.6.1 | Microbiological: sterility | I |
| 1.6.3 | Chemical/Physical | I |
| **S.1.8** | **Blinding of medicinal products for clinical trials** | |

* 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, **27.01.2020** (dd.mm.yyyy)
**No. GMP-CH-1000807**

Swissmedic, Swiss Agency for Therapeutic Products

Dr. Georges Meseguer