

## CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Schwabe Pharma AG, Erlistrasse 2, 6403 Küsnacht am Rigi**,  
Authorisation No. 512770-102678387 with its site **Schwabe Pharma AG, Erlistrasse 2, 6403 Küsnacht am Rigi, Switzerland**, Site No. 1000719 has been duly authorised to distribute medicinal products resp. API / intermediates according to the table below;

that the company is keeping the required level for Good Distribution Practices for Medicinal Products (GDP) according to the Swiss regulations in force. These regulations are in accordance with the requirements of the following documents:

- Guidelines of the European Commission on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01)
- Commission Implementing Regulation (EU) 2021/1248 on Good Distribution Practice for Veterinary Medicinal Products
- Guidelines of the European Commission on Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01)
- Commission Implementing Regulation (EU) 2021/1280 on Good Distribution Practice for active substances for veterinary medicinal products

that the company is subject to official periodic inspections; the last regular inspection has been performed on **01.12.2022** (dd.mm.yyyy).

| No.          | Operation   | Scope* |
|--------------|---|--------|
| <b>S.2</b>   | <b>IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b>                 |        |
| <b>S.2.1</b> | <b>Import of non- ready-to-use medicinal products</b>                               |        |
| S.2.1.1      | Medicinal products (intermediates, without immunological and blood products)        | H/V    |
| S.2.1.4      | Active substances   | H/V    |
| <b>S.2.2</b> | <b>Import of ready-to-use medicinal products, including market release</b>          |        |
| S.2.2.1      | Medicinal products (without immunological and blood products)                       | H/V    |
| <b>S.2.5</b> | <b>Storage of medicinal products by sales representatives</b>                       | H/V    |
| <b>S.2.6</b> | <b>Outsourcing of manufacture of medicinal products as contract giver</b>           | H/V    |
| <b>S.4</b>   | <b>WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b> |        |
| <b>S.4.1</b> | <b>Wholesale distribution of non- ready-to-use medicinal products</b>               |        |
| S.4.1.1      | Medicinal products (intermediates, without immunological and blood products)        | H/V    |
| S.4.1.4      | Active substances   | H/V    |



| No.          | Operation  | Scope* |
|--------------|--|--------|
| <b>S.4.2</b> | <b>Wholesale distribution of ready-to-use medicinal products, including market release</b> |        |
| S.4.2.1      | Medicinal products (without immunological and blood products)                              | H/V    |
| <b>S.4.5</b> | <b>Storage of medicinal products by sales representatives</b>                              | H/V    |
| <b>S.4.6</b> | <b>Outsourcing of manufacture of medicinal products as contract giver</b>                  | H/V    |
| <b>S.5</b>   | <b>EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b>                        |        |
| <b>S.5.1</b> | <b>Export of non- ready-to-use medicinal products</b>                                      |        |
| S.5.1.1      | Medicinal products (intermediates, without immunological and blood products)               | H/V    |
| S.5.1.4      | Active substances  | H/V    |
| <b>S.5.2</b> | <b>Export of ready-to-use medicinal products</b>   |        |
| S.5.2.1      | Medicinal products (without immunological and blood products)                              | H/V    |
| <b>S.5.3</b> | <b>Outsourcing of manufacture of medicinal products as contract giver</b>                  | H/V    |

\* 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, **13.02.2023** (dd.mm.yyyy)  
No. **GDP-CH-1004039**

Swissmedic, Swiss Agency for  
Therapeutic Products



*J. Büchi*

Jacqueline Büchi