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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Schwabe Pharma AG, Erlistrasse 2, 6403 Küssnacht am Rigi,** Authorisation No. 512770-102678387 with its site **Schwabe Pharma AG, Erlistrasse 2, 6403 Küssnacht am Rigi, Switzerland,** Site No. 1000719 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 **01.12.2022** (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)	
1.2.1.5	Liquids for external use	H/V
1.2.1.6	Liquids for internal use	H/V
1.2.1.8	Other solid dosage forms	H/V
1.2.1.17	Other non-sterile medicinal product: Homoeopathic globules and liquid dosage forms	H/V
1.2.2	Batch certification (technical release)	H/V
1.3	**Biological medicinal products**	
1.3.1	Biological Medicinal Products	
1.3.1.6	Human or animal extracted products	H/V
1.3.2	Batch certification (technical release)	
1.3.2.6	Human or animal extracted products	H/V
1.4	**Other products or manufacturing activity**	
1.4.1	Manufacture of:	
1.4.1.1	Herbal products	H/V
1.4.1.2	Homoeopathic products	H/V
1.5	**Packaging**	
1.5.1	Primary packaging	
1.5.1.5	Liquids for external use	H/V
1.5.1.6	Liquids for internal use	H/V
1.5.1.8	Other solid dosage forms	H/V
1.5.1.13	Tablets	H/V
1.5.1.17	Other non sterile medicinal products: Homoeopathic globules and liquid dosage forms	H/V
1.5.2	Secondary packaging	H/V

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No.	Operation	Scope*
1.6	**Quality control testing**	
1.6.3	Chemical/Physical	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. GMP-CH-1004039

Swissmedic, Swiss Agency for Therapeutic Products

Jacqueline Büchi

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