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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Hänseler AG, Industriestrasse 35, 9100 Herisau,** Authorisation No. 511619-102719232 with its site **Hänseler AG, Industriestrasse 35, 9100 Herisau, Switzerland,** Site No. 1000468 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/USA and Switzerland;

that from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **08.09.2023** (dd.mm.yyyy) , it is considered that it complies with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada/USA and Switzerland;

that 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.

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, I
1.2.1.6	Liquids for internal use	H/V, I
1.2.1.8	Other solid dosage forms	H/V, I
1.2.1.11	Semi-solids	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	
1.5.1.2	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
1.5.1.11	Semi-solids	H/V, I

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No.	*Operation*	*Scope**
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
S.1.8	**Blinding of medicinal products for clinical trials**	H/V, I
3	**MANUFACTURE OF ACTIVE SUBSTANCES**	
3.1	**Manufacture of active substance by chemical synthesis**	
3.1.1	Manufacture of active substance intermediates	H/V
3.1.2	Manufacture of crude active substance	H/V
3.1.4	Other: Preparation of active ingredient solutions from a chemical solid	H/V
3.2	**Extraction of active substance from natural sources**	
3.2.1	Extraction of substance from plant source	H/V, I
3.2.2	Extraction of substance from animal 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
3.8	List of active substances: Arnicae tinctura Carduus marianus tinctura Droserae extractum liquidum Farfara tinctura Fumaria officinalis tinctura Myrrhe tinctura Matricariae extractum liquidum normatum Opii tinctura normata Pelargonium sidoides tinctura Valerianae tinctura	-

* 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

Bern, **23.04.2024** (dd.mm.yyyy)
No. GMP-CH-1005697

Swissmedic, Swiss Agency for Therapeutic Products

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J. Büchi

Jacqueline Büchi

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