

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Hänseler AG, Industriestrasse 35, 9100 Herisau**, Authorisation No. 511619-102662194 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 and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **04.06.2021** (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)	
1.2.1.5	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
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

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

Berne, 20.10.2021 (dd.mm.yyyy)
No. GMP-CH-1002620

Swissmedic, Swiss Agency for
Therapeutic Products




Patricia Bellwald