

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **SPAGYRIK Produktions AG, Bachweg 3, 3400 Burgdorf**, Authorisation No. 511739-102621233 with its site **SPAGYRIK Produktions AG, Bachweg 3, 3400 Burgdorf, Switzerland**, Site No. 1001006 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 **13.07.2018** (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
1.2.1.11	Semi-solids	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
1.4.1.3	Other: Anthroposophic medicines	H/V
1.5	Packaging	
1.5.1	Primary packing	
1.5.1.5	Liquids for external use	H/V
1.5.1.6	Liquids for internal use	H/V
1.5.1.11	Semi-solids	H/V
1.5.2	Secondary packing	H/V
1.6	Quality control testing	
1.6.3	Chemical/Physical	H/V
The authorised activity is restricted to homeopathic drugs, spagyric drugs and phytotherapeutics		
3	MANUFACTURE OF ACTIVE SUBSTANCES	
3.2	Extraction of active substance from natural sources	
3.2.1	Extraction of substance from plant source	-

No.	Operation	Scope*
3.2.2	Extraction of substance from animal source	-
3.2.4	Extraction of substance from mineral source	-
3.5	General finishing steps	
3.5.2	Primary packaging	-
3.5.3	Secondary packaging	-
3.6	Quality control testing of medicinal products	
3.6.1	Physical / Chemical testing	-
3.8	List of active substances: Spagyrika, homeopathica and phytotherapeutica	-

* 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, **24.02.2020** (dd.mm.yyyy)
No. GMP-CH-1000891

Swissmedic, Swiss Agency for
 Therapeutic Products




 Dr. Federico Cimini