swissmedic

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Alpinamed AG, 9325 Roggwil TG,** Authorisation No. 511118-102719394 with its site **Alpinamed AG Werk I, Alte Landstrasse 11, 9306 Freidorf TG, Switzerland,** Site No. 1000612 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 **16.06.2023** (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)	
1.2.1.1	Capsules, hard shell	H/V
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
1.2.1.11	Semi-solids	H/V
1.2.1.13	Tablets	H/V
1.2.2	Batch certification (technical release)	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	
1.5.1.1	Capsules, hard shell	H/V
1.5.1.5	Liquids for external use	H/V
1.5.1.6	Liquids for internal use	H/V

Swissmedic | Hallerstrasse 7 | CH-3012 Bern | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

swissmedic

No.	Operation	Scope*
1.5.1.8	Other solid dosage forms	H/V
1.5.1.11	Semi-solids	H/V
1.5.1.13	Tablets	H/V
1.5.2	Secondary packaging	H/V
1.6	**Quality control testing**	
1.6.3	Chemical/Physical	H/V
3	**MANUFACTURE OF ACTIVE SUBSTANCES**	
3.2	**Extraction of active substance from natural sources**	
3.2.1	Extraction of substance from plant source	H/V
3.2.6	Purification of extracted substance: plant	H/V
3.5	**General finishing steps**	
3.5.1	Physical processing steps: concentrating, drying, milling, sieving, blending, filtration	H/V
3.5.2	Primary packaging	H/V
3.5.3	Secondary packaging	H/V
3.6	**Quality control testing**	
3.6.1	Physical / Chemical testing	H/V
3.8	List of active substances: Extract of Symphytum off. 1:2, PA purified	-

* 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, **28.02.2024** (dd.mm.yyyy)
No. GMP-CH-1005490

Swissmedic, Swiss Agency for Therapeutic Products

Swiss Agency for Therapeutic Products swissmedic

Laila Saxena

Swissmedic | Hallerstrasse 7 | CH-3012 Bern | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12


Swiss Agency for Therapeutic Products
swissmedic