

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **GELPELL AG**, **9533 Kirchberg SG**, Authorisation No. 512513-102659801 with its site **GELPELL AG**, **Kirchbergerstrasse 10**, **9534 Gähwil**, **Switzerland**, Site No. 1004735 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 18.08.2021 (dd.mm.yyyy).

No.	Operation	Scope*
1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
1.5	Packaging	
1.5.1 1.5.1.1 1.5.1.2 1.5.1.13 1.5.2	Primary packaging Capsules, hard shell Capsules, soft shell Tablets Secondary packaging	H/V H/V H/V
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 Veterinary medicinal products only, without investigational products

I Human investigational medicinal products

Not specified

Berne, **02.11.2021** (dd.mm.yyyy) **No. GMP-CH-1002642**



Swissmedic, Swiss Agency for Therapeutic Products

Marianne Baumann