

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Alpex Pharma SA, Via Cantonale, 6805 Mezzovico**, Authorisation No. 512424-102669086 with its site **Alpex Pharma SA, Via Cantonale, 6805 Mezzovico, Switzerland**, Site No. 1001152 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 **02.12.2021** (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)	
1.2.1.1	Capsules, hard shell	H/V, I
1.2.1.8	Other solid dosage forms	H/V, I
1.2.1.13	Tablets	H/V, I
1.2.2	Batch certification (technical release)	H/V, I
1.5	Packaging	
1.5.1	Primary packaging	
1.5.1.1	Capsules, hard shell	H/V, I
1.5.1.8	Other solid dosage forms	H/V, I
1.5.1.13	Tablets	H/V, I
1.5.2	Secondary packaging	H/V, I
1.6	Quality control testing	
1.6.2	Microbiological: non-sterility	H/V, I
1.6.3	Chemical/Physical	H/V, I
1.6.4	Biological	H/V, I
S.1.8	Blinding of medicinal products for clinical trials	

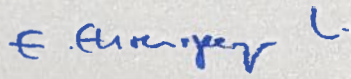
* Scope of authorisation:

- 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, 04.01.2022 (dd.mm.yyyy)
No. GMP-CH-1002877

Swissmedic, Swiss Agency for
Therapeutic Products




Eva Ehrensperger Murri