

CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Alpen Pharma AG, Finkenhubelweg 16, 3012 Bern**, Authorisation No. 512066-102648206 with its site **Alpen Pharma AG, Finkenhubelweg 16, 3012 Bern, Switzerland**, Site No. 1100183 has been duly authorised to distribute medicinal products resp. API / intermediates according to the table below;


that the company is keeping the required level for Good Distribution Practices for Medicinal Products (GDP) according to the Swiss regulations in force. These regulations are in accordance with the requirements of the Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) of the European Commission and with the requirements of the European GMP Part II (Basic Requirements for Active Substances used as Starting Materials);

that the company is subject to official periodic inspections; the last regular inspection has been performed on **18.09.2020** (dd.mm.yyyy).

No.	Operation
S.2	IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)
S.2.2	Import of ready-to-use medicinal products, including market release
S.2.2.1	Medicinal products (without immunological and blood products)
S.2.6	Outsourcing of manufacture of medicinal products as contract giver
	The authorised activities for import do not include the storage of medicinal products
S.5	EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)
S.5.2	Export of ready-to-use medicinal products
S.5.2.1	Medicinal products (without immunological and blood products)
S.5.3	Outsourcing of manufacture of medicinal products as contract giver
	The authorised activities for export do not include the storage of medicinal products

Berne, **23.02.2021** (dd.mm.yyyy)
No. GDP-CH-1001893

Swissmedic, Swiss Agency for
Therapeutic Products



Marianne Baumann