

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Oligopharm SA, Route de Montheron 8b, 1053 Cugy VD**, Authorisation No. 511438-102611229 with its site **Oligopharm SA, Route de Montheron 8b, 1053 Cugy VD, Switzerland**, Site No. 1001379 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 **08.10.2020** (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
1.2.1.6	Liquids for internal use	H/V
1.2.2	Batch certification (technical release)	H/V
1.4	Other products or manufacturing activity	
1.4.1	Manufacture of:	
1.4.1.3	Other: Intermediates products in the form of liquid preparation (limited to trace element solutions) and in solid form (limited to the filling of hard capsules)	H/V
1.5	Packaging	
1.5.1	Primary packing	
1.5.1.1	Capsules, hard shell	H/V
1.5.1.6	Liquids for internal use	H/V
1.5.2	Secondary packing	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
- V Veterinary medicinal products only, without investigational products
- I Human investigational medicinal products
- Not specified