

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Valsynthese SA, 3900 Brig-Glis**, Authorisation No. 511864-102626067 with its site **Valsynthese SA, Fabrikstrasse 48, 3900 Brig, Switzerland**, Site No. 1002528 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 **11.12.2020** (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)	
1.2.1.5	Liquids for external use	H/V, I
1.2.1.6	Liquids for internal use	H/V, I
1.2.1.11	Semi-solids	H/V
1.5	Packaging	
1.5.1	Primary packaging	
1.5.1.5	Liquids for external use	H/V, I
1.5.1.6	Liquids for internal use	H/V, I
1.5.1.11	Semi-solids	H/V, I
1.5.2	Secondary packaging	H/V, I
1.6	Quality control testing	
1.6.3	Chemical/Physical	H/V, I
3	MANUFACTURE OF ACTIVE SUBSTANCES	
3.1	Manufacture of active substance by chemical synthesis	
3.1.1	Manufacture of active substance intermediates	-
3.1.2	Manufacture of crude active substance	-
3.1.3	Salt formation / Purification steps: Extraction, distillation, UK, filtration/centrifugation	-
3.5	General finishing steps	
3.5.1	Physical processing steps: Drying, grinding, sieving	-
3.5.2	Primary packaging	-
3.5.3	Secondary packaging	-

No.	Operation	Scope*
3.6	Quality control testing	
3.6.1	Physical / Chemical testing	-

* 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, **31.03.2021** (dd.mm.yyyy)
No. GMP-CH-1002018

Swissmedic, Swiss Agency for
Therapeutic Products



Marianne Baumann