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# CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Société Suisse des Explosifs SA, 3900 Brig-Glis,** Authorisation No. 511863-102626065 with its site **Société Suisse des Explosifs SA, Fabrikstrasse 48, 3900 Brig, Switzerland,** Site No. 1002524 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 | - |



Swissmedic | Hallerstrasse 7 | CH-3012 Bern | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

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| 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-1002019**

Swiss Agency for Therapeutic Products swissmedic

Swissmedic, Swiss Agency for Therapeutic Products

M. Baumann

Marianne Baumann



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