

## CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **alcosuisse ag, Industriestrasse 10, 3295 Rüti bei Büren**, Authorisation No. 512229-102645911 with its site **Alcosuisse AG Betrieb Delémont, Route de la Communance 58, 2800 Delémont, Switzerland**, Site No. 1100734 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 **24.01.2020** (dd.mm.yyyy).

No.	Operation	Scope*
<b>3</b>	<b>MANUFACTURE OF ACTIVE SUBSTANCES</b>	
<b>3.3</b>	<b>Manufacture of active substance using biological processes</b>	
3.3.5	Other: adjustment of concentration, denaturation	-
<b>3.5</b>	<b>General finishing steps</b>	
3.5.2	Primary packaging	-
<b>3.6</b>	<b>Quality control testing</b>	
3.6.1	Physical / Chemical testing	-
3.8	List of active substances: Ethanol	-

\* 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, **24.01.2021** (dd.mm.yyyy)  
**No. GMP-CH-1001824**

Swissmedic, Swiss Agency for  
 Therapeutic Products




Jacqueline Büchi