

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **E. Brunner AG, Hauptstrasse 1, 8162 Steinmaur**, Authorisation No. 512304-102646957 with its site **E. Brunner AG, Hauptstrasse 1, 8162 Steinmaur, Switzerland**, Site No. 1000781 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 from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **30.08.2022** (dd.mm.yyyy) , it is considered that it complies with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland.

That this certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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)	
1.2.1.6	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: Plant extract medicinal products	H/V
1.6	Quality control testing	
1.6.3	Chemical/Physical	H/V

The authorised manufacturing operations are restricted to plant extracts and medicinal products of dispensing categories D and E.

No.	Operation	Scope*
3	MANUFACTURE OF ACTIVE SUBSTANCES	
3.2	Extraction of active substance from natural sources	
3.2.1	Extraction of substance from plant source	

* 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, 17.08.2023 (dd.mm.yyyy)
No. GMP-CH-1004732

Swissmedic, Swiss Agency for
 Therapeutic Products



J. Büchi

Jacqueline Büchi

SWISSMEDIC

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **E. Brunner AG, Hauptstrasse 1, 8162 Steinmaur**, Authorisation No. 512304-102646957 with its site **E. Brunner AG, Unterwerkstrasse 10, 8162 Steinmaur, Switzerland**, Site No. 1100596 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 from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **30.08.2022** (dd.mm.yyyy) , it is considered that it complies with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland.

That this certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection.

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No.	Operation	Scope*
1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	H/V
1.4	Other products or manufacturing activity	
1.4.1	Manufacture of:	
1.4.1.3	Other: The authorised operations are restricted to the storage of medicinal products.	
3	MANUFACTURE OF ACTIVE SUBSTANCES	-
3.7	Other activities: The authorised operations are restricted to the storage of medicinal products.	

* 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

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