

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **UFAG Laboratorien AG, Kornfeldstrasse 4, 6210 Sursee**, Authorisation No. 512955-102697858 with its site **UFAG Laboratorien AG Wirkstoffherstellung, Merkurstrasse 1, 6210 Sursee, Switzerland**, Site No. 1000260 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 **21.12.2022** (dd.mm.yyyy).

No.	Operation	Scope*
3	MANUFACTURE OF ACTIVE SUBSTANCES	
3.1	Manufacture of active substance by chemical synthesis	
3.1.2	Manufacture of crude active substance	H/V
3.5	General finishing steps	
3.5.1	Physical processing steps: Spray drying of solutions	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

Berne, **11.05.2023** (dd.mm.yyyy)
No. GMP-CH-1004322

Swissmedic, Swiss Agency for
Therapeutic Products



J. Büchi

Jacqueline Büchi