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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Frike Pharma AG, Auenstrasse 11, 8617 Mönchaltorf,** Authorisation No. 512409-102653200 with its site **Frike Pharma AG, Auenstrasse 11, 8617 Mönchaltorf, Switzerland,** Site No. 1006407 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 **01.04.2021** (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
1.2.1.6	Liquids for internal use	H/V
1.2.1.8	Other solid dosage forms	H/V
1.2.1.11	Semi-solids	H/V
1.2.2	Batch certification (technical release)	H/V
1.3	**Biological medicinal products**	
1.3.1	Biological Medicinal Products	
1.3.1.8	Other biological medicinal products: Processing API Tyrothricin	H/V
1.3.2	Batch certification (technical release)	
1.3.2.8	Other biological medicinal products: Processing API Tyrothricin	H/V
1.5	**Packaging**	
1.5.1	Primary packaging	
1.5.1.5	Liquids for external use	H/V
1.5.1.6	Liquids for internal use	H/V
1.5.1.8	Other solid dosage forms	H/V
1.5.1.11	Semi-solids	H/V
1.5.2	Secondary packaging	H/V
1.6	**Quality control testing**	
1.6.3	Chemical/Physical	H/V

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

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No.	Operation	Scope*

* 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, **24.10.2021** (dd.mm.yyyy)
No. GMP-CH-1002627

Swissmedic, Swiss Agency for Therapeutic Products

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