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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Frike Pharma AG, Auenstrasse 11, 8617 Mönchaltorf,** Authorisation No. 512409-102756750 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/USA and Switzerland;

that from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **03.04.2025** (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/USA 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 SwissGMDP/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)	
1.2.1.5	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

No.	*Operation*	*Scope**
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
1.6.4	Biological	H/V

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

* 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

Bern, **10.09.2025** (dd.mm.yyyy)

No. GMP-CH-1007521

Swissmedic, Swiss Agency for Therapeutic Products.