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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Pentapharm AG, Dornacherstrasse 112, 4147 Aesch BL,** Authorisation No. 512928-102724938 with its site **Pentapharm AG, Dornacherstrasse 112, 4147 Aesch BL, Switzerland,** Site No. 1106477 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 **12.01.2024** (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.

No.	*Operation*	*Scope**
3	**MANUFACTURE OF ACTIVE SUBSTANCES**	
3.2	**Extraction of active substance from natural sources**	
3.2.2	Extraction of substance from animal source	H/V
3.4	**Manufacture of sterile active substance**	
3.4.1	Aseptically prepared	H/V
3.5	**General finishing steps**	
3.5.2	Primary packaging	H/V
3.5.3	Secondary packaging	H/V
3.6	**Quality control testing**	
3.6.1	Physical / Chemical testing	H/V
3.6.2	Microbiological: testing (excluding sterility testing)	H/V
3.6.4	Biological Testing	H/V
3.8	List of active substances: Aprotinin Concentrated Solution, Aprotinin Solution, Haemocoagulase Solution, Batroxobin Concentrate Liquid, Batroxobin Concentrate	-

Swissmedic | Hallerstrasse 7 | CH-3012 Bern | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

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* 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, **24.05.2024** (dd.mm.yyyy)
No. GMP-CH-1005795

Swissmedic, Swiss Agency for Therapeutic Products

Daniela Althaus

Swiss Agency for Therapeutic Products
swissmedic

Swissmedic | Hallerstrasse 7 | CH-3012 Bern | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12