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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **BACHEM AG, Hauptstrasse 144, 4416 Bubendorf,** Authorisation No. 512123-102762534 with its site **BACHEM AG, Hauptstrasse 144, 4416 Bubendorf, Switzerland,** Site No. 1001480 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 **16.08.2024** (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.

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

No.	*Operation*	*Scope**
3	**MANUFACTURE OF ACTIVE SUBSTANCES**	
3.1	**Manufacture of active substance by chemical synthesis**	
3.1.1	Manufacture of active substance intermediates	H/V, I
3.1.2	Manufacture of crude active substance	H/V, I
3.1.3	Salt formation / Purification steps: Preparative HPLC, ultrafiltration, crystallization, countercurrent distribution	H/V, I
3.5	**General finishing steps**	
3.5.1	Physical processing steps: Lyophilisation, Drying, Milling, Concentrate	H/V, I
3.5.2	Primary packaging	H/V, I
3.5.3	Secondary packaging	H/V, I
3.5.4	Other: Dispensing	H/V, I
3.6	**Quality control testing**	
3.6.1	Physical / Chemical testing	H/V, I
3.6.2	Microbiological: testing (excluding sterility testing)	H/V, I
3.8	List of active substances: Antazoline Hydrochloride, Antazoline Phosphate, Antazoline Sulfate, Aprotinin Acetate, Atosiban Acetate, Bivalirudin, Buserelin, Calcitonin (salmon), Deslorelin High Acetate, Glucagon, Gonadorelin Acetate, Goserelin Acetate, Histrelin	-

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No.	Operation	Scope*
	Acetate, Icatibant Acetate, Leuprolide Acetate, Nitisinone, Octreotide Acetate, Palopegteriparatide, Somatostatin, Tetracosactide, Triptorelin Acetate, Triptorelin Pamoate	

* 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, **15.01.2026** (dd.mm.yyyy)
No. GMP-CH-1007998

Swissmedic, Swiss Agency for Therapeutic Products

Swiss Agency for Therapeutic Products swissmedic

J. Büchi

Jacqueline Büchi

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