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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Bachem SA, succursale de Vionnaz, Route du Simplon 22, 1895 Vionnaz,** Authorisation No. 512278-102714124 with its site **Bachem SA, succursale de Vionnaz, Route du Simplon 22, 1895 Vionnaz, Switzerland,** Site No. 1003100 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 from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **31.08.2023** (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 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 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
3.1.2	Manufacture of crude active substance	H/V
3.1.3	Salt formation / Purification steps: Cristallization, precipitation	H/V
3.5	**General finishing steps**	
3.5.1	Physical processing steps: Sieving, grinding, micronising	H/V
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
3.8	List of active substances: - Acenocoumarol - 5-Aminolevulinic acid HCl - Carbidopa - Darifenacin HBr - Etomidate - Fimaporfin di-olamine	-

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No.	Operation	Scope*
	- Propofol - Viloxazine HCl	

* 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, **14.11.2023** (dd.mm.yyyy)
No. GMP-CH-1005071

Swiss Agency for Therapeutic Products swissmedic

Swissmedic, Swiss Agency for Therapeutic Products

M. Baumann

Marianne Baumann

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