

## CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Bachem SA, succursale de Vionnaz, Route du Simplon 22, 1895 Vionnaz**, Authorisation No. 512278-102645786 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 the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **26.08.2021** (dd.mm.yyyy).

No.	Operation	Scope*
<b>3</b>	<b>MANUFACTURE OF ACTIVE SUBSTANCES</b>	
<b>3.1</b>	<b>Manufacture of active substance by chemical synthesis</b>	
3.1.1	Manufacture of active substance intermediates	-
3.1.2	Manufacture of crude active substance	-
3.1.3	Salt formation / Purification steps: Crystallization, precipitation	-
<b>3.5</b>	<b>General finishing steps</b>	
3.5.1	Physical processing steps: Sifting, grinding, micronising	-
3.5.2	Primary packaging	-
3.5.3	Secondary packaging	-
<b>3.6</b>	<b>Quality control testing</b>	
3.6.1	Physical / Chemical testing	-
3.8	List of active substances: - Acenocoumarol - 5-Aminolevulinic acid HCl - Benzoxonium chloride - Carbidopa - Darifenacin HBr - Etomidate - Fimaporfin di-olamine - Melarsomine 2HCl - Propofol - Trimetazidine dihydrochloride - 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, **08.10.2021** (dd.mm.yyyy)  
**No. GMP-CH-1002579**

Swissmedic, Swiss Agency for  
Therapeutic Products



Patricia Bellwald