Swissmedic Swiss Agency for Therapeutic Products

CERTIFICATE NUMBER: ***GMPE-CH-1005071***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued under the provisions of the Mutual Recognition Agreement between the European Union and ***Switzerland***.

The competent authority of Switzerland confirms the following:
The manufacturer: ***Bachem S.A. succursale de Vionnaz***
Site address: ***Route Du Simplon 22, Vionnaz, 1895, Switzerland, GPS: 46.306511, 6.907511***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011972 / LOC-100018864***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-08-31*** , it is considered that it complies with

The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union and ***Switzerland***

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. This certificate is valid only when presented with all pages and both Parts 1 and 2.

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

Part 2

Veterinary Medicinal Products
Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection:
SWISSMEDIC LIST OF APIS, SEE 4 ACTIVE SUBSTANCES(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:SWISSMEDIC LIST OF APIS, SEE 4 ACTIVE SUBSTANCES

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	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
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: stifting, grinding, mirconising 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

4. Other Activities - Active Substances:
5-Aminolevulinic acid HCl, Carbidopa, Darifenacin HBr, Etomidate, Fimaporfin di-olamine, Propofol, Viloxazine HCl

2023-11-14

Name and signature of the authorised person of the Competent Authority of Switzerland

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Confidential
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Tel:***Confidential***
Fax:***Confidential***