

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Akorn AG**, **Riethofstrasse 1, 8442 Hettlingen**, Authorisation No. 511345-102608628 with its site **Akorn AG**, **Riethofstrasse 1, 8442 Hettlingen, Switzerland**, Site No. 1101011 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 **04.07.2019** (dd.mm.yyyy).

No.	Operation	Scope*
1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
1.1	Sterile Products	
1.1.1	Aseptically prepared (processing operations for the following dosage forms)	
1.1.1.3	Semi-solids	H/V, I
1.1.1.4	Small volume liquids	H/V, I
1.1.3	Batch certification (technical release)	H/V, I
1.4	Other products or manufacturing activity	
1.4.2	Sterilisation of active substances / excipients / finished product	
1.4.2.1	Filtration	H/V, I
1.4.2.2	Dry heat	H/V, I
1.4.2.3	Moist heat	H/V, I
1.4.2.4	Chemical	H/V, I
1.4.2.5	Gamma irradiation	H/V, I
1.5	Packaging	
1.5.2	Secondary packing	H/V, I
1.6	Quality control testing	
1.6.1	Microbiological: sterility	H/V, I
1.6.2	Microbiological: non-sterility	H/V, I
1.6.3	Chemical/Physical	H/V, I
1.6.4	Biological	H/V, I
3	MANUFACTURE OF ACTIVE SUBSTANCES	
3.4	Manufacture of sterile active substance	
3.4.2	Terminally sterilised	-

No.	Operation	Scope*
3.5	General finishing steps	
3.5.1	Physical processing steps: Sterilization with dry heat, steam, chemical, gamma irradiation	-
3.5.2	Primary packaging	-
3.5.3	Secondary packaging	-
3.6	Quality control testing of medicinal products	
3.6.1	Physical / Chemical testing	-
3.6.2	Microbiological: testing (excluding sterility testing)	-
3.6.3	Microbiological: testing (including sterility testing)	-
3.6.4	Biological Testing	-

* 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, **25.11.2019** (dd.mm.yyyy)
No. GMP-CH-1000626

Swissmedic, Swiss Agency for
 Therapeutic Products




 Dr. Georges Meseguer