

## CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Siegfried AG, Untere Brühlstrasse 4, 4800 Zofingen, Switzerland** has been duly authorized to manufacture and distribute medicinal products, investigational medicinal products and active pharmaceutical ingredients, the manufacturing licence excluding sterile products and including following dosage forms:

- liquid dosage forms (including highly active or sensitising APIs)
- solid dosage forms (including highly active or sensitising APIs)

and following types of active pharmaceutical ingredients:

- highly active or sensitising APIs

including following activities:

- Quality control (chemical, physical and biochemical) of medicinal products as contract laboratory

that the finished medicinal products put on the market in Switzerland by the company are subject to appraisal and authorisation by our agency;

that the company is keeping the required level for good practices in the manufacture of pharmaceutical products and active pharmaceutical ingredients 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) and the Directives of the European Commission;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **June 14-16 and 19-21, 2017**;

that the requirements regarding manufacture and quality control for pharmaceutical products and active pharmaceutical ingredients for export are identical to those applicable to products sold in Switzerland.

Berne, July 13, 2017  
No. 17-1289

Swissmedic, Swiss Agency for  
Therapeutic Products



  
Michel Keller

# LEGALIZACIÓN

Gilbert Mürger, notario del cantón de Berna (Suiza), inscrito en el registro de notarios del cantón de Berna, con oficina en Berna,

autentica:

La fotocopia disponible corresponde con la copia que fue presentada al notario.

Autenticado en la oficina del notario en Berna el veinte de septiembre de dos mil diecisiete.

20 de septiembre de 2017



El notario:

*V. An*

APOSTILLE (Convention de La Haye du 5 octobre 1961)	
1. Pais: Confederación Suiza, Cantón de Berna El presente documento público	
2. ha sido firmado por <u>Gilbert Mürger</u>	
3. actuando en calidad de <u>notario</u>	
4. se halla sellado / timbrado con <u>Notaria del</u> <u>cantón de Berna</u>	
Certificado	
5. en Berna	6. el <u>25/09/2017</u>
7. por <u>Anna Beyeler</u>	
funcionario / a de la Cancillería de Estado del cantón de Berna	
8. con el número: <u>9025</u>	
9. Sello / timbre	10. Firma <u>A. Beyeler</u>



Tasa: CHF 25.-

