

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Siegfried Evionnaz SA, Route du Simplon 1, 36, 1902 Evionnaz, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) and investigational active pharmaceutical ingredients;

that the manufacturing licence is including following types of active pharmaceutical ingredients (APIs):

- investigational active pharmaceutical ingredients

that the company is manufacturing following API(s):

- Benoxinate hydrochloride
- Benzonatate
- Bethanechol chloride
- Bupivacaine base
- Bupivacaine hydrochloride
- Carisoprodol
- Chloroprocaine hydrochloride
- Choline salicylate 80 %
- Levonordefrin base
- Levonordefrin hydrochloride
- Mepivacaine hydrochloride
- Methenamine hippurate
- Methylphenidate hydrochloride
- Metolazone
- Oxybutynin base
- Oxybutynin hydrochloride
- Phenelzine sulfate
- Prilocaine base
- Prilocaine hydrochloride
- Ribavirin
- Tetracaine base
- Tetracaine hydrochloride
- Tricaine methanesulfonate
- BMS-14-Apixaban (Apixaban)
- BMS-28-Dasatinib (Dasatinib)
- BMS-29-Entecavir (Entecavir)
- BMS-30-Fosinopril (Fosinopril)
- BMS-33-Amide (Asunaprevir)

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs) and investigational 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 **January 23-25, 2018**;

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

Berne, February 24, 2020
No. 20-0123

Swissmedic, Swiss Agency for
Therapeutic Products

Dr. Georges Meseguer





APOSTILLE
(Convention de la Haye du 5 octobre 1961)



1. Pais: CONFEDERACIÓN SUIZA,

El presente documento público

2. ha sido firmado por Georges Meseguer

3. actuando en calidad de funcionario

4. se halla sellado/timbrado con Swissmedic

Instituto suizo de los productos terapéuticos

Certificado

5. en Berna

6. el

28. Feb. 2020

7. por Gaëlle Cafaro-Vullierat
funcionaria de la Cancillería de la Confederación Suiza

8. con el número.....004688

9. Sello/timbre

10. Firma

Cancillería de la Confederación Suiza



Tasa CHF 20.-