

TO WHOM IT MAY CONCERN

GMP certificates: no expiry date

Swissmedic, Swiss Agency for Therapeutic Products may issue **GMP certificates** on manufacturers of medicinal products and/or active pharmaceutical ingredients located in Switzerland.

We hereby confirm that there is no expiry date on these GMP certificates. These certificates are valid as long as no amendments to the corresponding establishment license on which a GMP certificate is based have been made. These certificates always contain two dates: the date of the last inspection and the date of issue of the certificate. The GMP certificate reflects the status of the manufacturing site at the time of the inspection and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

Vifor SA, Route de Moncor 10, 1752 Villars-sur-Glâne, Switzerland

We confirm, that the next inspection of the site **Vifor AG, Zweigniederlassung Medichemie Ettingen, Brühlstrasse 50, 4107 Ettingen, Switzerland** will be performed on August 16-18, 2016.

The current GMP certificates issued after the inspection conducted December 10-12, 2013 retain validity until the next inspections and for a limited period of time thereafter until the new GMP certificates have been issued.

Berne, June 27, 2016

Swissmedic
Swiss Agency for Therapeutic Products

A large, stylized blue ink signature of Dr. Alfred Ryt, written over the text of his name.

Dr. Alfred Ryt

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Vifor SA**, Route de Moncor 10, 1752 Villars-sur-Glâne, Authorisation No. 511101-102612043 with its site **Vifor SA Zweigniederlassung Medichemie Ettingen**, Brühlstrasse 50, 4107 Ettingen, Switzerland, Site No. 1000663 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 **08.05.2019** (dd.mm.yyyy).

No.	Operation	Scope*
1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
1.2	Non-sterile products	
1.2.1	Non-sterile products (processing operations for the following dosage forms)	
1.2.1.6	Liquids for internal use	H/V, I
1.2.1.11	Semi-solids	H/V, I
1.2.1.12	Suppositories	H/V, I
1.2.2	Batch certification (technical release)	H/V, I
1.5	Packaging	
1.5.1	Primary packing	
1.5.1.6	Liquids for internal use	H/V, I
1.5.1.11	Semi-solids	H/V, I
1.5.1.12	Suppositories	H/V, I
1.5.2	Secondary packing	H/V, I
1.6	Quality control testing	
1.6.3	Chemical/Physical	H/V, I

* 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, **28.08.2019** (dd.mm.yyyy)
No. GMP-CH-1000392

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 - 3. Okt. 2019
7. por Alessandra Maniero
funcionaria de la Cancillería de la Confederación Suiza
8. con el número..... 023888
9. Sello/timbre 10. Firma



Cancillería de la Confederación Suiza

A. Maniero

Alessandra Maniero