

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Ferring International Center SA, Chemin de la Vergognausaz 50, 1162 Saint-Prex**, Authorisation No. 511100-102630933 with its site **Ferring International Center SA, Chemin de la Vergognausaz 50, 1162 Saint-Prex, Switzerland**, Site No. 1001627 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 **07.05.2021** (dd.mm.yyyy).

No.	Operation	Scope*
1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
1.1	Sterile Products	
1.1.3	Batch certification (technical release)	H/V
1.2	Non-sterile products	
1.2.1	Non-sterile products (processing operations for the following dosage forms)	
1.2.1.8	Other solid dosage forms	H/V, I
1.2.1.12	Suppositories	H/V, I
1.2.1.13	Tablets	H/V, I
1.2.2	Batch certification (technical release)	H/V
1.3	Biological medicinal products	
1.3.2	Batch certification (technical release)	
1.3.2.5	Biotechnology products	H/V
1.3.2.6	Human or animal extracted products	H/V
1.5	Packaging	
1.5.1	Primary packaging	
1.5.1.8	Other solid dosage forms	H/V, I
1.5.1.12	Suppositories	H/V, I
1.5.1.13	Tablets	H/V, I
1.5.2	Secondary packaging	H/V
1.6	Quality control testing	
1.6.2	Microbiological: non-sterility	H/V, I
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, **24.08.2021** (dd.mm.yyyy)

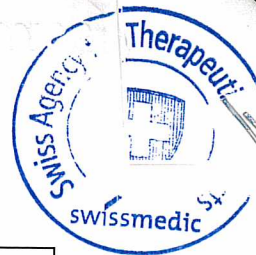
No. GMP-CH-1002448

Swissmedic, Swiss Agency for
Therapeutic Products

E. Ehrensperger

Eva Ehrensperger Murri





APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. Pais: CONFEDERACIÓN SUIZA,

El presente documento público

2. ha sido firmado por Eva Ehrensperger Murri

3. actuando en calidad de funcionaria

4. se halla sellado/timbrado con Swissmedic

Instituto suizo de los productos terapéuticos

Certificado

5. en Berna

6 el

08. Sep. 2021

7. por Alessandra Manoiero

funcionaria de la Cancillería de la Confederación Suiza

8. con el número.....

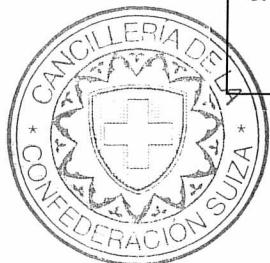
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9. Sello/timbre

10. Firma

Cancillería de la Confederación Suiza

A. Manoiero



Tasa CHF 20.-