

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Proto Chemicals AG, Glarus Süd** with its site **Proto Chemicals AG, Tschachen 2, 8756 Mitlödi, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) and medicinal products;

that the company is manufacturing following API(s): Tramadol Hydrochloride

that the company is performing the following activities:

- secondary packing of medicinal products

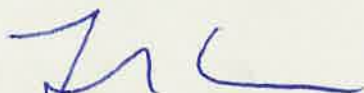
that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs) and medicinal products according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality 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 **February 12-13, 2020**;

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

Berne, December 16, 2020
No. 20-0687

Swissmedic, Swiss Agency for
Therapeutic Products



Dr. Federico Cimini





APOSTILLE
(Convention de la Haye du 5 octobre 1961)

1. Pais: CONFEDERACIÓN SUIZA,

El presente documento público

2. ha sido firmado por Federico Cimini

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 **22. Dez. 2020**

7. por Alessandra Manoiero
funcionaria de la Cancilleria de la Confederación Suiza

8. con el número.....**026768**.....

9. Sello/timbre

10. Firma

Tasa CHF 20.-

Cancilleria de la Confederación Suiza

A. Manoiero

