

CERTIFICATE OF GMP COMPLIANCE

(for the Health Authorities of Chile)

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), the manufacturing licence excluding sterile API

including following packaging activities:

- Secondary packaging of medicinal products

that the company manufactures following API(s): Tramadol Hydrochloride

that the company is keeping the required level for good practices in the manufacture of 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 **March 22-24, 2016**;

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

Berne, September 12, 2016
No. 16-1773

Swissmedic, Swiss Agency for
Therapeutic Products

Dr. Alfred Ryt





APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. Pais: CONFEDERACIÓN SUIZA,

El presente documento público

2. ha sido firmado por Alfred Ryf

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 13 de septiembre de 2016

7. por Yvonne Agosti

funcionaria de la Cancillería de la Confederación Suiza

8. con el número.....019634.....

9. Sello/timbre

10. Firma

Cancillería de la Confederación Suiza