

CERTIFICATE OF GMP COMPLIANCE

(for the Health Authorities of Chile)

We certify herewith

that the company **CARBOGEN AMCIS AG, Hauptstrasse 171, 4416 Bubendorf, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients and medicinal products;

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

- highly active or sensitising APIs
- biological APIs such as
 - APIs produced by means of recombinant technologies, hybridoma and monoclonal antibodies restricted to the conjugation of biological APIs
- investigational active pharmaceutical ingredients

that the company is manufacturing following API(s): Brinzolamid

that the company is performing the following activities:

- quality control (chemical, physical, biochemical) of medicinal products as contract laboratory

that the finished medicinal products put on the market in Switzerland by the company are subject to appraisal and authorisation by our agency;

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients 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 **May 2-4, 2017**;

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

Berne, May 16, 2018
No. 18-1074

Swissmedic, Swiss Agency for
Therapeutic Products



Dr. Alfred Ryf

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

17. MAI 2018

7. por Yvonne Agosti
funcionaria de la Cancillería de la Confederación Suiza

011206

8. con el número.....

9. Sello/timbre

10. Firma

Cancillería de la Confederación Suiza



Tasa CHF 20.-