

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Alpex Pharma SA, Via Cantonale, 6805 Mezzovico-Vira, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients, medicinal products and investigational medicinal products;

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

- investigational active pharmaceutical ingredients

that the company is manufacturing the following dosage forms:

- solid dosage forms
- investigational medicinal products

that the company is performing the following activities:

- primary packing of medicinal products
- secondary packing of medicinal products
- packaging of investigational medicinal products
- quality control (chemical, physical and biochemical) of medicinal products as contract laboratory
- quality control (biological) of medicinal products as contract laboratory
- quality control (microbiological) of medicinal products as contract laboratory excluding tests of sterility

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, medicinal products and investigational 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 **December 5-6, 2017**;

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

Berne, January 8, 2018
No. 17-2448

Swissmedic, Swiss Agency for
Therapeutic Products



Dr. Alfred Ryt