

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), medicinal products and investigational medicinal products;

that the company is manufacturing the following dosage forms:

- solid dosage forms
- investigational medicinal products
 - including solid dosage forms
 - including randomisation

that the company is performing the following activities:

- primary packing of medicinal products (non-sterile)
 - including solid dosage forms
- secondary packing of medicinal products including randomisation of medicinal products for clinical trials
- 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), 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 3-4, 2019**;

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

Berne, February 6, 2020
No. 20-0084

Swissmedic, Swiss Agency for
Therapeutic Products

Dr. Georges Meseguer

