

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **IBR Inc., Institute for Biopharmaceutical Research, Lauchefeld 31, 9548 Matzingen, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) and medicinal products;

that the company is performing the following activities:

- quality control (chemical, physical) 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 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 **November 1, 2018**;

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, February 1, 2019
No. 19-0101

Swissmedic, Swiss Agency for
Therapeutic Products



Dr. Alfred Ryf

