

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **alcosuisse ag, Länggassstrasse 35, 3012 Bern** with its site **Alcosuisse AG, Betrieb Schachen, Schachenweidstrasse 2, 6105 Schachen, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs);

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs) 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 **October 24, 2017**;

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

Berne, February 19, 2018
No. 18-0370

Swissmedic, Swiss Agency for
Therapeutic Products




Dr. Alfred Ryf