

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Senn Chemicals AG, Guido Senn-Strasse 1, 8157 Dielsdorf, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) and investigational active pharmaceutical ingredients;

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

- investigational active pharmaceutical ingredients

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs) and investigational active pharmaceutical ingredients 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 **August 21-23, 2018**;

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

Berne, November 5, 2018
No. 18-2273

Swissmedic, Swiss Agency for
Therapeutic Products



Dr. Alfred Ryf