

## CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Solvias AG, Römerpark 2, 4303 Kaiseraugst** with its site **Solvias AG, Mattenstrasse 22, 4002 Basel, Switzerland**, has been duly authorized to manufacture 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 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 **July 3-4, 2019**;

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

Berne, September 30, 2019  
**No. 19-1194**

Swissmedic, Swiss Agency for  
Therapeutic Products



D. Alfred Ryf

