

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Simec Service GmbH, Eggenacherstrasse 48, 4663 Aarburg** with its site **Simec Service GmbH, Areal Bleiche West, 4800 Zofingen, Switzerland**, has been duly authorized to manufacture and distribute medicinal products, the manufacturing licence including following packaging activities:

- Primary packaging of medicinal products [being restricted to active pharmaceutical ingredients (APIs)]

that the company is keeping the required level for good practices in the manufacture of pharmaceutical products and 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 **October 14, 2015**;

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

Berne, August 15, 2016
No. 16-1638



Swissmedic, Swiss Agency for
Therapeutic Products

Dr. Alfred Rytz