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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Simec AG, 4800 Zofingen** with its site **Simec AG, Areal Bleiche West, 4800 Zofingen, Switzerland**, has been duly authorized to manufacture medicinal products, the manufacturing licence including following activities:

- Quality control (chemical, physical and biochemical) 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 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 inspection was conducted on **April 19-20, 2011**;

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, June 20, 2011
No. 11-927

Swiss Agency for Therapeutic Products swissmedic

Swissmedic, Swiss Agency for Therapeutic Products

Dr. Alfred Ryf

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
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