

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Temmentec AG** with its site of **Lütoldstrasse 6, 3454 Sumiswald, Switzerland**, has been duly authorized to manufacture and distribute medicinal products, the manufacturing licence excluding sterile products and including following dosage forms:

- liquid dosage forms
- semi-solid forms

and following packaging activities:

- Primary packaging of medicinal products
- Secondary packaging of medicinal products

that the finished medicinal products put on the market in Switzerland by the company are subject to appraisal and authorisation by our agency;

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 **August 13, 2003**;

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.

Bern, September 13, 2005
No. 05-990

Swissmedic, Swiss Agency for
Therapeutic Products




Dr. Tobias Godtschan

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