

## CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **DOTTIKON EXCLUSIVE SYNTHESIS AG** with its site of **Hembrunnstrasse 17, 5605 Dottikon, Switzerland**, has been duly authorized to manufacture and distribute medicinal products, investigational medicinal products and active pharmaceutical ingredients, the manufacturing licence excluding sterile products and including following dosage forms:

- liquid dosage forms (including - highly active or sensitising products)
- solid dosage forms (including - highly active or sensitising products)

and following types of active pharmaceutical ingredients:

- highly active or sensitising 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 **July 29, 2009**;

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 14, 2009  
No. **09-1619**

Swissmedic, Swiss Agency for  
Therapeutic Products



Michel Keller

