

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **APR Applied Pharma Research SA** with its site of **Via Corti 5, 6828 Balerna, Switzerland** has been duly authorized to manufacture medicinal products, the manufacturing licence including following activities as contract laboratory:

- Quality control (chemical, physical and biochemical) of medicinal products

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 **October 23, 2008**;

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, February 17, 2009
No. **09-381**

Swissmedic, Swiss Agency for
Therapeutic Products



Dr. Georges Meseguer