

15. 30

瑞士

SWISSmedic

Q GMP Certificate 未檢本字號

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company _____ with its site of _____ Switzerland, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs), the manufacturing licence excluding sterile API and including following APIs:

in 7A

that the company is keeping the required level for good practices in the manufacture of 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 February 08-09, 2011;

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

Berne, September 30, 2011

Swissmedic, Swiss Agency for Therapeutic Products

